UNION EUROPEENNE

Bruxelles,
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Subject: **EU comments to the report of the meeting of the OIE Code Commission – 6 / 17 September 2010**

Dear Director General,

Please find attached, an annex indicating the European Union comments on the report of the Terrestrial Animal Health Commission meeting of September 2010.

I trust you will find this useful.

Thank you for your continued cooperation.

Yours sincerely,

Dr. Pierre Naessens
CVO – AFSCA
Delegate of Belgium to the OIE

Dr. Bernard Van Goethem
Deputy Director General (acting)
DG Health and Consumers – EC

Annex: 1

Copy: All Directors/Chief Veterinary Officers of the EU and Croatia, Iceland, Liechtenstein, Norway, Switzerland and Turkey.

Dr. B. Vallat
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ANNEX

Original: English
September 2010

REPORT OF THE MEETING OF THE
OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 6–17 September 2010

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The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at the OIE Headquarters in Paris from 6 to 17 September 2010.

The members of the Code Commission are listed in Annex I and the agenda adopted is in Annex II.

The Code Commission reviewed the documents identified in the agenda, addressing comments that Members had submitted by August 6 2010 and amended texts in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) where appropriate. The amendments are shown in the usual manner by double underline and ~~strikeout~~ and may be found in the Annexes to the report. In Annexes XX (bee diseases), the amendments made at this meeting (September 2010) are shown with a coloured background to distinguish them from those made prior to the 78th OIE General Session in May 2010.

Members should note that, unless stated otherwise, texts submitted for comment may be proposed for adoption at the 79th OIE General Session. Depending on the comments received on each text, the Code Commission will identify the texts proposed for adoption in May 2011 in the report of its February 2011 meeting.

The Code Commission strongly encourages Members to participate in the development of the OIE's international standards by submitting comments on this report. It would be very helpful if comments were submitted as specific proposed text changes, supported by a scientific rationale. Proposed deletions should be indicated in '~~strikeout'~~ and proposed additions with 'double underline'. Members **should not use the automatic 'track-change' function** provided by word processing software as such changes are lost in the process of collating Members' submissions into the Code Commission's working documents. In order to be considered at the meetings of the *ad hoc* Group on Veterinary Education, comments on Annex XXXVI should reach OIE Headquarters by **10 December 2010**. Other comments on this report must reach OIE Headquarters by **7 January 2011** to be considered at the February 2011 meeting of the Code Commission. All comments should be sent to the International Trade Department at: trade.dept@oie.int.

A. MEETING OF THE DIRECTOR GENERAL WITH THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Dr Vallat, Director General of the OIE, met with the two Commissions for a discussion on the significant elements of the two meetings.

With reference to the work of the *ad hoc* Group on FMD, Dr Vallat asked the two Commissions to work in a coordinated manner on this. Dr Vallat expressed the view that the adopted text on the protection zone and the FMD Chapter was well established. The OIE was organising a second Global Conference on FMD, in collaboration with the FAO. The Conference would be held in 2012. Under the new provisions in the *Terrestrial Code*, non FMD-free Members would be encouraged to present their national FMD control programme to the OIE for endorsement. The OIE endorsement of a national FMD control programme would be a key consideration for donors and should be widely publicised, including at the second Global Conference on FMD, which would also be a pledging meeting. Dr Bruckner

indicated that the Scientific Commission for Animal Diseases (the Scientific Commission) would give to the Code Commission a new draft article dealing with endorsement of national control programmes. On the protection zone, while the definition would not be modified, new text had been proposed dealing with the implementation of protection zones.

Dr Vallat mentioned the OIE Global Rabies Conference, which would take place on 7–9 September 2011 in Seoul, and encouraged both Commissions to progress the review of the rabies chapter.

Dr Vallat also mentioned the OIE Global Conference on Veterinary Legislation and stated that this would provide an important opportunity for strengthening references to OIE standards in the national legislation of OIE Members.

In regard to veterinary drugs and vaccines, Dr Vallat recalled the fact that the OIE had a major influence in the creation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The OIE support for VICH was important and this is reflected in the hosting of the VICH Conference at OIE headquarters in June 2010. The membership of VICH was primarily developed countries and at the moment it did not have a globally representative scope. The countries of Latin America, through the Committee of the Americas for the Harmonisation of the Registration and Control of Veterinary Medicines (CAMEVET), have asked the OIE to develop standards on the labelling of veterinary drugs. Noting that this work could fall within the mandate of the Biological Standards Commission, Dr Vallat stated that he would request views from relevant Specialist Commissions on how best to move forward, including the possibility of greater involvement of VICH.

Dr Thiermann reaffirmed that the Code Commission would remove from the *Terrestrial Code* all chapters and references on diseases that have been delisted. Relevant information e.g. on diagnostic procedures would of course be retained in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*).

On the listing of diseases, the development of the OIE's work into the domain of wildlife has very significant implications for the OIE classification of diseases and for the structure of the *Terrestrial Code*. The chapter dealing with the disease list should be revised accordingly. The *Terrestrial Code* should be restructured, perhaps based on an alphabetical listing of the disease agents.

Dr Bruckner advised that a document on the wildlife/livestock interface had been drafted by the Wildlife Working Group and the *ad hoc* Group on Epidemiology would be given to the Code Commission for review.

B. JOINT MEETING OF THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION

The two Commissions held a meeting to discuss the following key points.

Definition of Wildlife

The Code Commission explained its proposed modification of the definition drafted by the Wildlife Working Group and the Scientific Commission agreed to the approach outlined.

Infected zone

Dr Bruckner explained the concerns of the Scientific Commission in regard to the current definition in the Glossary: 'a zone in which a disease has been diagnosed'. Dr Bonbon explained the Code Commission thinking on this problem, which takes into account that not all disease chapters of the *Terrestrial Code* contain specific provisions on infected countries/zones.

Dr Thiermann proposed that a definition of 'undetermined status' could be included, using the text proposed by the Scientific Commission, i.e. 'the absence of the disease under consideration has not been demonstrated based on the requirements specified in the *Terrestrial Code*.

Case definition of OIE listed diseases

Dr Bruckner enquired about the Code Commission approach to providing a case definition in each disease chapter. It was agreed that a case definition should be provided in all disease chapters and that this would be done gradually, as disease chapters are updated, including ensuring alignment and harmonisation with the definitions in the *Terrestrial Manual.*

EU comment

The EU commends this approach.

Disease notification and listing

The two Commissions discussed several points in the report of the recent meeting of the *ad hoc* Group on Disease Notification and Listing. Both Commissions expressed concerns about the proposed use of the words 'potential for international spread' in place of the existing text 'has international spread been proven'. This was considered to widen the scope for listing diseases beyond what is considered acceptable.

It was agreed that the title of the chapter should be modified to 'Criteria for reporting and listing disease' and that more detailed guidance should be provided on the criteria for reporting emerging diseases and new epidemiological events, particularly when occurring in wildlife. The Code Commission undertook to review the report, which it received earlier in the week, and address the concerns of the Scientific Commission during this review.

EU comment

The EU agrees with this approach and is waiting for a global update of the chapter.

Compartmentalisation

Dr Bruckner advised that the ad hoc Group on Epidemiology had developed a generic checklist on the implementation of a compartment. Dr Thiermann noted that the existing checklist on compartmentalisation for avian influenza and Newcastle disease was well accepted by Members and constituted the key practical reference for countries wishing to apply compartments at the present time. He reiterated that Members had identified the need for a checklist on the specifics of application of a compartment for FMD. The Code Commission undertook to review the draft generic checklist and give feedback to the Scientific Commission.

OIE endorsed national FMD control programme

Noting the importance of this new OIE initiative, the Code Commission agreed to review the draft text provided by the Scientific Commission.

Principles for defining a protection zone

Dr Thiermann provided a copy of the Code Commission's revision of the draft text on establishing protection zones, which had been provided by Scientific Commission. Dr Thiermann explained the revisions to this text. The Scientific Commission noted the revised text provided by the Code Commission and undertook to analyse it in detail.

Commodity trade

Dr Kahn noted that the last meeting of the *ad hoc* Group occurred in October 2009 and that there was a need to consider further work of the Group.

Rabies

The Code Commission noted the submission of a revised chapter on rabies and undertook to review this as a matter of priority.

Scrapie

The two Commissions discussed the issue of 'atypical' scrapie in terms of notification requirements and the issue of the host genetic resistance. In response to questions of Members, the Code Commission clarified that 'classical' scrapie is reportable to the OIE but that 'atypical' scrapie is not reportable (in accordance with the recommendations made by the *ad hoc* Group on Atypical Scrapie and Atypical BSE, which met in November 2007). However, the sharing of scientific information on 'atypical' scrapie is encouraged. At this time, the Code Commission considered that more scientific information would be needed to fully address the issues associated with host genotype.

EU comment

The EU takes note of the fact that atypical scrapie is not an OIE listed disease. Nevertheless, it will remain notifiable in the EU. Moreover it must be stressed that any emergence of this disease should be notified to the OIE by Members and that scientific data should continue to be gathered.

Labelling of veterinary drugs

The Scientific Commission proposed that the labelling of veterinary drugs be addressed using a similar approach as used for the OIE Guidelines on Veterinary Legislation.

Epizootic haemorrhagic disease

Dr Bruckner proposed that the Scientific Commission draft a chapter on *epizootic haemorrhagic disease* and send it to the Code Commission for consideration.

EU comment

The EU commends this initiative and is ready to share expertise.

Bee diseases

Dr Thiermann provided an update on the Code Commission's review of the revised chapters on bee diseases, explaining that several modifications had been made to the recommendations of the *ad hoc* Group, including removal of the compartmentalisation concept.

EU comment

The EU agrees with the removal of compartmentalisation in bees. However, the fact that it is proposed to replace it by "free apiaries" is unacceptable in the absence of strong risk mitigation measures.

Meeting dates

The dates for the September 2011 meeting of the two Commissions were discussed. The proposed dates for the Scientific Commission are 29 August to 4 September; the Code Commission agreed to make arrangements to facilitate active liaison between the two Commissions.

C. EXAMINATION OF MEMBER COMMENTS AND WORK OF RELEVANT EXPERT GROUPS

1. Update on reports of other commissions; harmonisation with the OIE *Aquatic Animal Health Code*; other relevant activities of the OIE

Dr Thiermann presented an overview of developments within the OIE for information of members.

2. Revision of the OIE *Terrestrial Animal Health Code*

Item 1. General comments

The Code Commission received a comment from the EU.

In response to this comment, the Code Commission stated that references to 'legally binding' in the report of the February 2010 meeting should be understood as the international obligations of the Members of the World Trade Organization under the Sanitary and Phytosanitary Agreement to base their sanitary measures on the standards set out in the *Terrestrial Code*.

Item 2. Glossary

The Code Commission received comments from the EU and the Scientific Commission.

Veterinary Services

The Code Commission noted that the EU comment (from the General Session held in 2010) had already been addressed by the International Trade Department.

Antimicrobial agent

The Code Commission noted a comment from the EU and made a revision to the definition to clarify the text.

Infected zone

The Code Commission noted a comment from the EU and the two options proposed to amend the definition. The Code Commission accepted the proposal to retain the definition as it stands and to request that the International Trade Department review the text of other chapters of the *Terrestrial Code* and, as appropriate, add the phrase 'for the purpose of this chapter'.

Veterinary legislation

The Code Commission proposed a new definition (see Item 7 Veterinary Services).

Wildlife

The Code Commission noted the recommendations of the Wildlife Working Group but did not see a necessity to define 'domestic animal' because the term 'animal' is already defined in the *Terrestrial Code* and definitions of the term 'domestic' (as applied to animals) are readily found in dictionaries. In addition, the word 'domestic' is not needed in the term 'feral domestic animal' as 'feral' clearly refers to an animal that has at some time been domesticated; therefore the Code Commission proposed to modify this to 'feral animal'. Finally, the Code Commission proposed to add a fourth definition, i.e.

'wildlife' - means any combination of feral animals, captive wild animals and wild animals.

EU comment

This definition adds more to confusion than it helps, because it could lead to different interpretations when the term is used in the chapters. Since there are definitions for each category of wildlife and if, as stated below, in all places in the Code where "wildlife" appears, it would be replaced by the correct term, this last one is unnecessary and should therefore be deleted.

The process proposed below would really improve the Code in better defining the diseases, the case, the notification, the role of each category of animals, etc.

If Members support this proposal, there will be a need to review the *Terrestrial Code* to decide the appropriate use of all defined terms in the *Terrestrial Code* chapters.

Euthanasia

The Code Commission added to the Glossary the definition of the term 'euthanasia' from Chapter 7.8. (Use of Animals in Research and Education). The term *euthanasia* is also used in Chapter 7.7. (Control of Stray Dog Populations). The definitions of euthanasia in Chapters 7.7. and 7.8. were deleted.

Euthanasia means the act of inducing *death* using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to the *animal*.

The revised Glossary, which is presented at Annex III, is provided for Member comments.

EU comment

The EU can support the proposed changes to the Glossary.

Item 3. Notification of diseases and epidemiological information and Criteria for listing diseases (Chapters 1.1. and 1.2.) – also see Part B

The Code Commission received comments from Australia, the EU and the USA.

The Code Commission met with Dr Karim Ben Jebara for a short discussion on the findings of the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents', which met on 29 June–1 July 2010. The Code Commission was informed that the *ad hoc* Group had recommended modifications to the decision tree in Chapter 1.2.

On the basis that the *ad hoc* Group recommended and the Scientific Commission supported the delisting of Teschovirus encephalomyelitis, the Code Commission again proposed to delete Chapter 15.5.

The Code Commission accepted recommendations to delist leptospirosis, fowl cholera and Marek's disease and noted that this would lead to removal of the names of these diseases from Article 1.2.3. and the deletion of Chapters 10.9. and 10.12. in May 2011.

Noting that duck virus enteritis and avian tuberculosis are not listed diseases, the Code Commission proposed to delete Chapters 10.6. and 10.7.

The Code Commission looked forward to receiving a marked up text showing proposed changes to the decision tree in Chapter 1.2. as the basis for proposing modifications to Members.

In response to Members' comments, the Code Commission proposed to modify Article 1.1.3., on immediate notification, making reference to the relevant provisions in the specific disease chapters.

Re-ordering of disease chapters according to name of the pathogen

In the context of the development of global policies on the interface between human health and animal health, including the role of wild animals, and proposed changes to the OIE requirements for notification of diseases of domestic animals and wildlife, the Code Commission saw a need for reconsideration of the structure of Volume 2 of the *Terrestrial Code*. An appropriate option would be to structure the list of diseases in Article 1.2.3 and Volume 2 according to the scientific name of the disease (e.g. Chapter 11.6. 'Bovine Tuberculosis' to be renamed '*M. bovis* infection'). The Commission asked the International Trade Department to prepare a proposal for consideration at its next meeting.

The revised Chapters, which are presented at Annex IV, are provided for Member comments.

EU comment

The EU can support the proposed changes to the Chapters 1.1 and 1.2, to the deletion of chapters, and encourages the TAHSC and OIE Headquarters in their work to restructure the list of diseases.

Item 4. Animal health surveillance (Chapter 1.4.)

The Code Commission received advice from the Scientific Commission on previous comments from Australia.

The Code Commission noted these comments but did not make any modifications to the chapter (see discussion under Section B). The Code Commission noted the decision at the 78th OIE General Session (2010) to delete the definition "case definition" on the basis that the term is explained more clearly in point 2 e) of Article 1.4.3.

Item 5. Status for OIE listed diseases (Chapter 1.6.)

The Code Commission received new text on FMD and African horse sickness and questionnaires relevant to both diseases from the Scientific Commission (Note: see specific discussion on FMD and African horse sickness in the relevant items).

On the basis of text changes proposed at the Commission's February 2010 meeting and adopted at the 78th General Session in May 2010, no further changes were made to the introductory text (Article 1.6.1.) Changes proposed by the Scientific Commission on each questionnaire may be found in the Item on the relevant disease.

Item 6. OIE Import Risk Analysis Handbook

The Code Commission was informed that the revised edition of Volume I of the Handbook on Import Risk Analysis for Animals and Animal Products was close to completion and would be published late in 2010.

Item 7. Evaluation of Veterinary Services

The Code Commission received comments from the EU.

a) Revisions to Chapters 3.1. and 3.2.

The Code Commission agreed to the EU recommendation to include the words 'or animal welfare' in Article 3.1.1.

In regard to the recommendation, to add a definition of 'veterinary regulations' in Article 3.1.1., the Code Commission decided to include a definition in the Glossary of the term 'veterinary legislation' and delete "and regulation" from "veterinary legislation and regulation". The following definition was proposed:

Veterinary legislation means: laws, regulations and associated legal instruments that pertain to the veterinary domain.

The Code Commission referred to the OIE Animal Welfare Working Group a request from the EU for specific articles on animal welfare to be included in Chapter 3.2.

b) Global veterinary legislation initiative

Dr Kahn gave an update on the current state of play with the OIE Global Veterinary Legislation initiative. The Code Commission noted the progress of this important initiative. Bearing in mind that the first Global Conference on Veterinary Legislation will take place in Djerba, Tunisia, on 7–9 December 2010, and that this is likely to generate interest on the part of OIE Members to address gaps in national veterinary legislation, the Code Commission considered that it would be appropriate to propose the Legislation Guidelines as a new standard, i.e. to incorporate them into the *Terrestrial Code* as Chapter 3.3.

Legislation Missions – As at 24 August 2010

Region	Official requests	Missions completed
Africa	16	7
Americas	2	0
Asia/Pacific	3	3
Europe	3	1
Middle-East	4	2

Total	**28**	**13**

Official requests:

Africa (16): *Benin, Burkina Faso,* Congo (DR), Djibouti, Ethiopia, *Gabon, Guinea-Bissau, Madagascar,* Malawi, Mauritania, Mauritius, Nigeria, Sudan, *Togo, Uganda,* Zambia

Americas (2): Bolivia, Honduras

Asia/Pacific (3): *Bhutan, Cambodia, Vietnam*

Europe (3): Armenia, Kazakhstan*, Kyrgyzstan*

Middle-East (4): Afghanistan, *Kuwait, Lebanon,* UAE

Italics: Completed missions

The new and revised Chapters, which are presented at Annex V, are provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 8. Design and implementation of identification systems to achieve animal traceability (Chapter 4.2.)

The Code Commission received comments from the EU and made some minor modifications in response.

The revised Chapter, which is presented at Annex VI, is provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 9. Zoning and compartmentalisation

a) Zoning and compartmentalisation (Chapter 4.3.)

The Code Commission received comments from Brazil, the *ad hoc* Group on Epidemiology and the Scientific Commission with advice on previous comments from the EU, the Comité Veterinario Permanente del CONOSUR (CVP).

The Code Commission agreed to the comment from the Scientific Commission regarding additional references to the role of susceptible wildlife species and made some appropriate changes to the text. The Code Commission noted and supported a Member's comments on Article 4.3.2.

The Code Commission noted that according to the definition established in the *Terrestrial Code*, the definition of animal identification encompasses both identification at the individual animal or the herd or flock level, hence the modification proposed by a Member in Point 2.a. of Article 4.3.3. was not accepted.

Noting that the goal of the *Terrestrial Code* is to help Members to implement the concept of zone/compartment, the Code Commission modified the title or Article 4.3.3. to read 'Principles for defining and establishing…'.

The Code Commission received new text dealing with the implementation of the protection zone, which had originated from a proposal made by the *ad hoc* Group on Epidemiology as modified by the Scientific Commission. The Code Commission noted that many points in the new draft text were already specifically covered in Article 4.3.3. The Code Commission carefully reviewed the new draft text and found some useful points that were not in the current text of Article 4.3.3., namely:

- One of the goals of a protection zone is to ensure early detection

- Animals in the protection zone should be clearly distinguishable from other sub populations
- Biosecurity should be increased
- Vector surveillance should be undertaken.

The text of Article 4.3.3. was amended to address these points.

The use of a protection zone is supported strongly by the OIE as this can help countries to control contagious diseases and to minimise trade disruption. However, the *Terrestrial Code* cannot make provisions that curtail the sovereignty of Members to make decisions in response to disease outbreaks in the territories of trading partners. In addition, the Code Commission wished to avoid introducing additional complex and potentially confusing provisions.

The Code Commission accepted a proposal of the Scientific Commission (based on a submission from the CVP) and modified the text on the containment zone accordingly.

b) Application of compartmentalisation (Chapter 4.4.)

The Code Commission received comments from Brazil and advice from the Scientific Commission on previous comments from the EU. The Code Commission accepted the comment of Brazil and made the relevant modification. The Code Commission noted the comments of the Scientific Commission and the EU but did not consider that text modifications were required as they would not improve the current version.

c) Update on compartmentalisation projects supported by the OIE

Dr Thiermann reported that he had undertaken a mission to Thailand to review the compartmentalisation project in that country. The focus of the project is to establish a compartment for broiler rearing establishments, and to appropriately manage the inputs and risks to the health status of this sector.

The Brazilian compartmentalisation project is advancing and Brazil has recently provided feedback to the OIE on the published checklist for avian influenza and Newcastle disease compartments. This information would be provided to the *ad hoc* Group on Epidemiology for information and any action required.

The revised Chapters, which are presented at Annex VII, are provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 10. Semen and embryos

a) Collection and processing of bovine, small ruminant and porcine semen (Chapter 4.6.)

The Code Commission removed references to Teschovirus encephalomyelitis (see Item 3).

The revised Chapter, which is presented at Annex VIII, is provided for Member comments.

EU comment

The EU can support the proposed changes.

b) Collection and processing of *in vitro* produced embryos / oocytes from livestock and horses (Chapter 4.8.)

The Code Commission received comments from Canada but did not accept the proposed modification because, by convention, 'should' is used rather than 'must' in the *Terrestrial Code*.

Item 11. Disposal of dead animals (Chapter 4.12.)

The Code Commission received comments from Canada, the EU and Japan.

The Code Commission noted that a Member's comment was no longer relevant as the chapter was adopted in May 2010. Members' recommendations for the OIE to review data pertaining to Article 4.12.6. were noted and the Code Commission requested the provision of new data that may be relevant to the bio-refining process. A Member's comment on this point was noted but not supported because it had been adopted on the basis of a peer reviewed scientific study.

Item 12. Veterinary certificate

a) General obligations related to certification (Chapter 5.1.)

The Code Commission received comments from Nigeria and Chile.

Members' comments on Chapter 5.1. were not considered by the Code Commission because specific text amendments, with supporting rationale, were not proposed.

b) Certification procedures (Chapter 5.2.)

The Code Commission received comments from EU and China (the People's Rep. of).

The Code Commission accepted the suggestion to replace the word 'notifiable' by 'notifiable diseases' in Article 5.2.1. paragraph 2, because 'notifiable diseases' is defined in the Glossary. The other proposals were not supported by the Code Commission because no rationale was provided for these and therefore the Code Commission was not able to understand the reasoning behind the proposed amendments.

The revised Chapter, which is presented at Annex IX, is provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 13. Control of hazards of animal health and public health importance in animal feed (Chapter 6.3.)

The Code Commission received comments from Australia, Canada and the OIE Animal Production Food Safety Working Group (APFSWG).

The Code Commission reviewed the comment of a Member and of the APFSWG regarding alignment with Codex definitions but did not agree to make any modifications to the text because it had recently been adopted by the World Assembly.

The Code Commission accepted to add 'infectious agent' to the definition of 'contamination' for clarification of Article 6.3.3. but did not accept to delete "unwanted", on the basis that some heavy metals, such as copper, may be beneficial or harmful depending on the chemical concentration. The Code Commission also accepted to make a minor change to point 12 of Article 6.3.4. 'Contamination'.

Noting the discussion in the *ad hoc* Group on Pet Food, the Code Commission accepted to modify point 8 of Article 6.3.4.

The revised Chapter, which is presented at Annex X, is provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 14. Control of OIE listed diseases in heat treated, shelf stable pet food – new draft chapter

The Code Commission received comments from the USA.

The Code Commission reviewed the report of the *ad hoc* Group on Pet Food, which met on 1–3 September 2010. Dr MacDiarmid, chair of the *ad hoc* Group, outlined the discussion in the *ad hoc* Group meeting and the basis for the recommendations provided to the Code Commission.

The Code Commission had several concerns about Table 1 in the draft text, largely arising from the fact that it draws upon multiple approaches to assuring the safety of pet food. The approaches fall into four categories, i.e.

- pathogens are not relevant to the raw material (e.g. avian influenza in products of porcine or bovine origin);
- the ingredient comprises safe commodities identified in the *Terrestrial Code* (e.g. skeletal muscle that meets the provisions of Article 11.5.1. for BSE);
- the ingredient is obtained from a safe source (e.g. FMD free countries/zones);
- the use of thermal processing to inactivate pathogens that may be present in the ingredient or product, based on current *Terrestrial Code* provisions.

Members of the Code Commission considered that the report of the *ad hoc* Group should be included as an annex to the Code Commission report. In addition, it decided to provide the proposed draft chapter for inclusion in Section 5 of the *Terrestrial Code* (Trade Measures, Import/Export Procedures and Veterinary Certification) as a clean text, on which Members would be asked to comment. The Code Commission amended Article 2 and Table 1 and annotated the table as 'under study', with a recommendation that this be revised to provide clear separation between recommendations based on current provisions in the *Terrestrial Code*.

The new Chapter, which is presented at Annex XI, is provided for Member comments. The report of the *ad hoc* Group is attached in Annex XXXIII for information of Members.

EU comment

The EU has important comments that should be taken into account by the TAHSC in its next meeting. The Chapter is not ready for adoption in its present version.

Item 15. Salmonellosis

a) Prevention, detection and control of *Salmonella* in poultry (Chapter 6.5.)

The Code Commission received comments from Brazil, China (People's Rep. of) and from the *ad hoc* Group on Salmonellosis, which met in May 2010. Comments previously provided by South Africa and not adopted at the 78th General Session were again reviewed and rejected by the Code Commission on the same grounds.

With respect to Members' comments on the use of antimicrobials to treat poultry for salmonellosis, the Code Commission recalled that several Members have previously made comments warning against the use of antimicrobials in poultry. The issue has been thoroughly considered and the current text was considered to be appropriate. The OIE standards on prudent use of antimicrobials should also be considered when prescribing antimicrobials for use in poultry.

The Code Commission did not accept an additional sentence in Article 6.5.4. point b) as it considered that it was redundant. The Code Commission amended a few points, including changing 'and/or' to 'or', based on recommendations of the *ad hoc* Group.

b) Biosecurity procedures in poultry production (revised Chapter 6.4.)

The Code Commission reviewed the amendments to the draft text that had been proposed by the *ad hoc* Group at its meeting in May 2010. The text was supported with some minor amendments. The Code Commission wished to remind Members that the purpose of this chapter is to provide guidance to Members that wish to improve biosecurity at poultry establishments with the goal of improving poultry health and productivity. To highlight this objective, the Code Commission added the phrase 'and is not specifically related to trade' to the first sentence of Article 6.4.1.

The revised Chapters, which are presented at Annex XII, are provided for Member comments. The report of the *ad hoc* Group is attached in Annex XXXIV for information of Members.

EU comment

The EU can support the proposed changes.

Item 16. Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.7.)

The Code Commission received comments from the EU.

As stated in the last report, all the OIE work on animal production food safety is conducted in active collaboration with the Codex Alimentarius Commission. Thus, there is no need to make a specific statement to this effect in individual articles in the *Terrestrial Code*.

Item 17. Animal welfare

a) Chapters on transport of animals (Chapters 7.3. and 7.4.)

The Code Commission received comments from Australia, China (People's Rep. of), the EU, and Korea (Rep. of).

In response to Members' comments on point 6 e) of Article 7.3.5., the Code Commission noted that the requirement to be able to observe individual animals would not normally apply to poultry and amended the text of Article 7.3.5.7 a) accordingly.

In response to a Member's question, the Code Commission noted that both long distance and short distance travel is covered in point 3 c) of Article 7.3.7.

The Code Commission noted that a Member's request for clarification about the need to observe poultry in transit [Point 7 a) Article 7.3.9.] had already been covered by the modification to the text in point 7a) of Article 7.3.5.

Specific provisions on chickens will be included in Article 7.3.12, dealing with species-specific issues.

EU comment

The EU thanks the OIE for this last version that it supports, but has comments that should be taken into account by the TAHSC in its next meeting.

b) Slaughter of animals (Chapter 7.5.)

The Code Commission received comments from China (People's Rep. of), Chinese Taipei, the EU, Japan and Korea (Rep. of).

The Code Commission agreed with the need, identified by Members, for inclusion of a text referring to the need for slaughterhouses to implement an animal welfare plan and included new text under point 1 of Article 7.5.2.

Point 1f)viii was changed to point 1g) in Article 7.5.2, reflecting the need to use performance standards generally; not only in relation to the use of goads and other aids.

The Code Commission disagreed with a Member who stated that it was acceptable for poultry with dislocated or broken legs and wings to be immediately shackled for processing, and maintained the original text in point 2 of Article 7.5.2.

The need for a waiting pen at high throughput slaughterhouses (as opposed to all slaughterhouses) was reflected in modified text in point 2 h) of Article 7.5.3.

Several recommendations made by Members were not accepted because the points that they raised were already adequately covered in the text. However, a number of minor text amendments were made to improve clarity.

EU comment

The EU thanks the OIE for this last version that it supports, but has comments that should be taken into account by the TAHSC in its next meeting.

c) Killing of animals for disease control purposes (Chapter 7.6.)

The Code Commission received comments from Brazil, Chinese Taipei and the EU.

The Code Commission requested that the Member which raised it provide a scientific rationale for the proposal to add 'Ducks and geese do not appear to be resilient to the effects of a mixture of 20% carbon dioxide and 80% nitrogen or argon' in points 4c) ii and 4d) of Article 7.6.12.

EU comment

The EU thanks the OIE for this last version that it supports, but has comments that should be taken into account by the TAHSC in its next meeting.

d) Stray dog population control (Chapter 7. 7.)

The Code Commission received comments from the EU and the *ad hoc* Group on Rabies, as endorsed by the Scientific Commission.

The Code Commission noted a proposal but did not agree to change 'control' to 'management' (several references within the text) because the goal of the chapter (as reflected in the title of the chapter) is control and the use of 'control' rather than 'management' had been discussed extensively previously.

The Code Commission modified the preamble, based on the input from the Scientific Commission.

Noting Members' comments on the definition of euthanasia, the Code Commission proposed to include in the Glossary the definition of euthanasia adopted in Chapter 7.8. (Use of Animals in Research and Education) in the 78th General Session and to remove the definition from Article 7.7.2.

With respect to the definition of 'stray dog', the Code Commission decided to leave the text unchanged, pending the final decision of OIE Members on the definitions of 'wildlife' to be included in the glossary.

The Code Commission modified entries in Table Article 7.7.6. for consistency.

References were removed from Article 7.7.8., in accordance with established practice. Noting that these references are valuable to Members, the Code Commission proposed that the OIE place a copy of Article 7.7.8., complete with updated references, on the OIE web site.

EU comment

The EU thanks the OIE for this last version that it supports, but has one comment that should be taken into account by the TAHSC in its next meeting.

e) Use of animals in research and education (Chapter 7.8.)

The Code Commission received comments from Chinese Taipei and the EU.

The Code Commission noted Members' comments calling for modification of terms such as 'committee', 'local committee' and 'ethics committee' in Chapter 7.8. The Commission noted that the goal of this chapter is to identify an overall framework for correct use of animals, and not to specify the detailed structure to be used. For this reason, the chapter provides for flexibility in selecting elements within the framework. The Commission did not see value in trying to achieve more specificity by qualifying 'committee' or other terms used in this chapter.

The Code Commission proposed to delete the definition of 'euthanasia' from Article 7.8.1. and include it in the Glossary.

The Code Commission modified the text of point 5 Article 7.8.7 to clarify the distinction between genetically altered and cloned animals.

EU comment

The EU thanks the OIE for this last version that it supports, but has comments that should be taken into account by the TAHSC in its next meeting.

f) Report of the OIE Animal Welfare Working Group (June 2010 meeting)

The Code Commission noted the report of the Animal Welfare Working Group (AWWG) and thanked members for their ongoing significant contribution to the OIE's standard setting work. The Code Commission appreciated the paper 'Guidance from the AWWG to *ad hoc* Groups on the development of animal welfare standards' and recommended that, subject to validation by Members, the International Trade Department provide this paper to all *ad hoc* Groups working on animal welfare.

EU comments

The EU welcomes the work carried out by the OIE Working Group on Animal Welfare to provide the *ad hoc* groups with guidance on the development of animal welfare standards and supports the proposed text.

There is a need to improve the possibility to implement the OIE standards on animal welfare with particular reference to those on livestock production being currently developed.

The report of the AWWG is attached in Annex XXXI for information of Members.

g) Report of the *ad hoc* Group on Animal Welfare and Broiler Chicken Production Systems

The Code Commission received comments from Korea (Rep. of).

The Code Commission noted the extensive revision of the draft chapter on animal welfare and broiler chicken production by the *ad hoc* Group and the comments of the AWWG on the draft text. The Commission noted that the AWWG had developed a paper (see point f) above) to guide the work of *ad hoc* Groups in the development of standards for livestock production systems. The Commission invited Members to comment on both the draft text on broilers and the AWWG Guidance paper, in order to consider these comments when drafting standards in the area of livestock production.

EU comment

See above comment concerning the guidance paper.

The EU has comments on the draft text on broilers that should be taken into account by the TAHSC in its next meeting or in the next meeting of the ad hoc group.

The Commission referred a Member's comment on the draft text on broiler chickens to the *ad hoc* Group for consideration at its next meeting.

The report of the *ad hoc* Group is attached in Annex XXXII for information of Members.

h) Animal welfare and beef production systems

The Code Commission received comments from Korea (Rep. of).

The Code Commission noted that the *ad hoc* Group will hold its next meeting early in 2011 and referred the comment to the *ad hoc* Group for consideration.

i) Proposal to use risk analysis principles in developing animal welfare standards

The Code Commission noted a submission from an individual in a Member country regarding the use of risk analysis and management principles to support the OIE's work in the development of animal welfare standards. The Code Commission did not recognise the relevance of this approach to the OIE's work and was uncertain to what extent the Delegate had supported the proposal.

j) Guidelines on the establishment of OIE Regional Animal Welfare Strategies.

The Code Commission noted the document submitted by the AWWG.

The revised Chapters, which are presented at Annex XIII, are provided for Member comments.

Item 18. Anthrax (Chapter 8.1.)

The Code Commission received comments from Australia, Brazil, the EU and New Zealand.

The Code Commission agreed to modify Articles 8.1.5. and 8.1.6. Article 8.1.10. was modified to include recommendations on the inactivation by moist heat of *B. anthracis* spores in bone meal and meat-and-bone meal. Modifications were based on scientific studies (Murray, 1931; Spotts Whitney, Beatty *et al.*, 2003). The Commission also modified Article 8.1.11. by adding a reference to the use of gamma irradiation as a means to inactivate *B. anthracis* spores in wool and hair. Scientific references were provided as follows:

T.J. Murray (1931). The thermal death point. *Journal of Infectious Diseases*. Vol 48 (5): 457– 467.

P. Turnbull P. & O. Cosivi. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE.

E.A. Spotts Whitney, M.E. Beatty, T.H. R.J. Taylor, R. Weyant, J. Sobel, M.J. Arduino & D.A. Ashford. (2003). Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases*, 9 (6), 623–627.

The revised Chapter, which is presented at Annex XIV, is provided for Member comments.

EU comment

The EU supports the proposed changes but has some comments.

Item 19. Aujeszky's disease (Chapter 8.2.)

The Code Commission received comments from the EU.

Based on Members' comments, the text of articles relating to disease surveillance was modified to be less prescriptive in terms of the recommendations on surveillance (Article 8.5.6. point b). The Code Commission understood that the 5-km radius was originally based on the expected movements of vectors, such as rodents. The Code Commission modified this recommendation as it considered that the national veterinary services were the best placed to evaluate the radius of the surveillance zone and this point was not amenable to a prescriptive approach.

The revised Chapter, which is presented at Annex XV, is provided for Member comments.

EU comment

The EU supports the proposed changes but has some comments.

Item 20. Bluetongue (Chapter 8.3.)

The Code Commission received comments from Australia and advice from the Scientific Commission on previous comments from Switzerland.

Based on advice from the Scientific Commission, the Code Commission created a new point 3 c) in Article 8.3.3. and a new point 6 in Article 8.3.8. In addition, the Code Commission included an explanation of the term 'vector protected' in Article 8.3.15. and used this to replace 'vector proof' throughout Chapter 8.3., as was done for Chapter 12.1. (African horse sickness).

The revised Chapter, which is presented at Annex XVI, is provided for Member comments.

EU comment

The EU cannot support some of the proposed changes, if the TAHSC does not take into account its comments in its next meeting.

Item 21. Foot and mouth disease

The Code Commission received comments from Australia, Chinese Taipei and the EU, and the Scientific Commission provided advice on previous comments of the CVP.

a) Chapter 8.5.

References throughout the chapter to FMD were checked as to whether 'FMDV' should be added. This modification was made to Article 8.5.5.

The Code Commission developed a new Article 8.5.7. *bis* on the provisions for an OIE endorsed national FMD control programme, based on the text drafted by the Scientific Commission and modified by the Code Commission.

Modifications proposed by the CVP and supported by the Scientific Commission, were adopted in the introduction to Article 8.5.5. and in point 1c).

The Code Commission did not agree to Members' proposals for modifications to the text of point 2 of Article 8.5.8. because it considered that the *Terrestrial Code* already provided an appropriate level of flexibility in the definition of stamping out and the control of disease relating to a containment zone.

With reference to Article 8.5.41., Dr Bruckner informed the Code Commission that the advice that the processes which make small ruminant and porcine casings safe are also effective for beef casings is based on a personal communication to the Scientific Commission by experts (Dr M. Beer and Dr J. Wijnker) of the European Natural Sausage Casings Association.

The Code Commission proposed to merge Articles 8.5.22., 23. and 24. because the risks and conditions are equivalent in these three articles.

b) Revised FMD questionnaire

At a Member's suggestion, the Scientific Commission proposed to modify the text of the questionnaire on FMD. The Code Commission provided the revised text to Members for comment.

c) OIE endorsement of a national FMD control programme

The Code Commission reviewed the text of revisions to Chapter 8.5. and to the associated questionnaire provided by the Scientific Commission and made several modifications, based on the following key considerations:

- The proposed text addresses the provisions for OIE endorsement of a Member's national FMD control strategy. Within this national strategy the implementation of measures in zones or in the entire national territory may be envisaged. However, the OIE endorsed programme applies throughout the national territory, not solely in a zone.

- Countries requesting OIE approval of their control programme should be encouraged to follow the OIE PVS Pathway.

- The measures implemented under the national programme should be consistent with the provisions in the *Terrestrial Code*, particularly in Chapters 8.5. and 1.1. (Disease reporting).

The draft questionnaire was modified to reflect the revisions made to the draft text and to correct English grammar. Notably, the questionnaire was modified to be consistent with the concept of an OIE endorsed FMD control programme as a national programme, although measures may be implemented at the level of a zone rather than the entire national territory.

The revised Chapters, which are presented at Annex XVII, are provided for Member comments.

EU comment

The EU has important comments that should be taken into account by the TAHSC in its next meeting.

Item 22. Rabies

a) Chapter 8.10. (Rabies)

The Code Commission reviewed the revised text of Chapter 8.10. drafted by an *ad hoc* Group and agreed by the Scientific Commission.

The entire text was revised for consistency with the approach in the *Terrestrial Code*.

The Code Commission noted the need for accuracy in naming host species such as dogs, cats and ferrets in light of the new definition of 'wildlife'.

The text was modified to clarify that Chapter 8.10. deals with infection of domestic dogs, cats and ferrets with the species *rabies virus* in the genus *Lyssavirus*.

To facilitate review by Members, the revised chapter was presented as a clean text.

b) Model international veterinary certificate for dogs and cats originating from rabies infected countries (Chapter 5.11.)

The draft certificate for domestic dogs, cats and ferrets was modified to reflect the amendments made to Chapter 8.10.

The revised Chapters, which are presented at Annex XVIII, are provided for Member comments.

EU comment

The EU has strong comments that should be taken into account by the TAHSC in its next meeting.

Item 23. Vesicular stomatitis (Chapter 8.15.)

The Code Commission reviewed comments from New Zealand received at the previous meeting and modified Article 8.15.6. accordingly.

The revised Chapter, which is presented at Annex XIX, is provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 24. Diseases of bees (Chapter 4.14 and Chapters 9.1. to 9.6.)

The *ad hoc* Group on Diseases of Bees reviewed comments submitted previously by Members and reviewed the revised Chapter 4.14. (Hygiene and Disease Security Procedures in Apiaries) and comments on Chapters 9.1. to 9.6. that had been provided by the *ad hoc* Group on Diseases of Bees.

a) Hygiene and disease security procedures in apiaries (Chapter 4.14.)

The Code Commission noted the *ad hoc* Group proposal for new work on *Nosema ceranae* and, as the disease is not currently listed by the OIE, recommended that the status of *N. ceranae* be considered by the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents at its next meeting.

The Code Commission considered that the text of Chapter 4.14. should be confined to general recommendations and disease specific recommendations should be relocated to the relevant disease chapter. Accordingly the Code Commission removed the text in point 1a) of Article 4.14.3. and placed it in a new Article 9.6.4. *bis* (varroosis). The text in point 1b) of Article 4.14.3. was retained with an appropriate modification.

It was agreed that the recommendations in Chapter 4.14. should be referenced in Chapters 9.1. to 9.6. inclusive.

In agreement with the *ad hoc* Group on Diseases of Bees, the Code Commission considered that the concept of 'compartment' was not applicable to honey bees because bees are free-ranging and therefore it is not possible to implement management controls to prevent them coming into direct contact with bees of a different health status. Therefore the reference to a compartment was removed from all bee disease chapters.

b) Acarapisosis of honey bees (Chapter 9.1.)

The Code Commission received comments from the *ad hoc* Group on Diseases of Bees on previous comments from the EU.

'Extracted honey, pollen, propolis, royal jelly for human consumption and processed beeswax' were added to the list of safe commodities in Article 9.1.2. and the words 'honey bee collected' were removed.

c) American foulbrood (Chapter 9.2.) and European foulbrood (Chapter 9.3.)

The Code Commission received comments from the *ad hoc* Group on Diseases of Bees on previous comments from the EU and Canada.

A modification was made to include a reference to Article 4.14.3.

d) Small hive beetle infestation (*Aethina tumida*) (Chapter 9.4.)

The Code Commission received comments from the *ad hoc* Group on Diseases of Bees on previous comments from Australia, the EU and Switzerland.

The Code Commission accepted the recommendations and made several modifications to the text, including the addition of a reference to Article 4.14.3.

e) *Tropilaelaps* infestation of honey bees (Chapter 9.5.)

The Code Commission received comments from the *ad hoc* Group on Diseases of Bees on previous comments from the EU.

'Extracted honey, pollen, propolis, royal jelly for human consumption and processed beeswax' were added to the list of safe commodities in Article 9.5.2. and the words 'honey bee collected' were removed.

Article 9.5.1 was modified by replacing '7 days' with '21 days', to be consistent with the *ad hoc* Group's recommendations to modify this point in Articles 9.5.6., 7. and 8.

The Code Commission accepted Member comments and modified Articles 9.5.6., 9.5.7. and 9.5.8. by replacing '7 days' with '21 days'. In addition, point 3 of Article 9.5.8. was modified by adding the phrase 'recommended by the OIE (under study)' instead of the proposed reference to 'chapter X.X'.

f) Varroosis of honey bees (Chapter 9.6.)

The Code Commission received comments from the *ad hoc* Group on Diseases of Bees on previous comments from the EU and Switzerland.

Article 9.6.2. was revised to read 'Extracted honey, pollen, propolis, royal jelly for human consumption and processed beeswax'.

The Code Commission proposed a new Article 9.6.4. *bis*: a Varroa Free Establishment (apiary), containing the recommendation that the *ad hoc* Group had originally proposed in Article 4.14.3. point 1a), because the Code Commission considered that this provision should be included in the specific disease chapter rather than in Chapter 4.14. A reference to the provisions in Article 4.14.3. (Conditions for approval of breeding apiaries for export trade') was added to Article 9.6.4. *bis* as for other chapters on bee diseases.

Article 9.6.7. and Article 9.6.8. were modified by replacing '7 days' with '21 days', consistent with the *ad hoc* Group's recommendations.

The revised Chapters, which are presented at Annex XX, are provided for Member comments.

EU comment

The EU has strong comments that should be taken into account by the TAHSC in its next meeting. In particular, the fact that it is proposed to replace "compartments" by "approved apiaries" is unacceptable in the absence of strong risk mitigation measures.

Item 25. Avian influenza (Chapter 10.4.)

The Code Commission received comments from Australia, Brazil, the EU, and the Scientific Commission.

The Code Commission discussed Members' comments on additional clarity for disease notification and made minor modifications to the Chapter.

In regard to the inactivation of avian influenza:

- the Code Commission was advised by the author of the cited scientific paper that the correct value in Article 10.4.25 was in fact 870 seconds, not the 256 seconds suggested by Members. The 256 seconds was, according to the author, a typographical error;
- the Code Commission noted that the time cited by a Member with reference to Article 10.4.26. would achieve a 1 log reduction rather than the 7 log reduction achieved elsewhere in the chapter. Therefore, the proposal was not accepted.

The revised Chapter, which is presented at Annex XXI, is provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 26. Newcastle disease (Chapter 10.13.)

The Code Commission received comments from Brazil, the EU and the USA.

The Code Commission discussed Members' comments on additional clarity for disease notification. The Code Commission made minor modifications to the Chapter and recommended to add a sentence in

Article 1.1.3. referring the reader to the specific recommendations in the relevant disease chapter (see Item 3.)

In response to a question from Members, the Code Commission did not see a need to modify Chapter 10.13. to address the issue of post-vaccination reversion to virulence.

The revised Chapter, which is presented at Annex XXII, is provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 27. Bovine brucellosis (Chapter 11.3.)

The Code Commission noted that no progress had been made on the review of Chapter 11.3. and that the next meeting of the *ad hoc* Group on Brucellosis would be held in 2011.

Item 28. Bovine spongiform encephalopathy (Chapter 11.5.)

The Code Commission received comments from Argentina, Australia, Canada, Chinese Taipei, the EU, Japan, Korea (Rep. of), New Zealand and the USA.

The Code Commission agreed with comments from Members proposing that changes to the text should not be made in the absence of new, significant scientific information. As no comments presenting new scientific evidence had been submitted, the Code Commission decided not to modify the chapter.

A request for a text modification based on the potential risk of infectivity associated with the bovine intestine was referred to the Scientific Commission for scientific advice. The Code Commission noted that the Scientific Commission referred this question to the *ad hoc* Group on Bovine Spongiform Encephalopathy Risk Status Evaluation of Members.

Item 29. Bovine tuberculosis (Chapter 11.6.)

The Code Commission received comments from Australia and Swaziland and an advice from the Scientific Commission on previous comments from Switzerland.

The Code Commission referred to the Scientific Commission a Member's request to address tuberculosis in camelids, noting that this would need to be addressed by the *ad hoc* Group on Diseases of Camelids.

The Member's comment on *M. caprae* was not accepted because Chapter 11.6. deals with *M. bovis* infection. Again, the Code Commission referred this request to the Scientific Commission.

EU comment

The EU welcomes the new approach of listing diseases by pathogens and hopes that this would help to better define the diseases, e.g. *M. caprae* being a cause of tuberculosis in bovine.

Noting that the Scientific Commission did not accept a Member's comment on Article 11.6.4., no changes were proposed.

Item 30. Contagious bovine pleuropneumonia

The Code Commission agreed with a recommendation from the Scientific Commission to include a reference: 'bovine semen, embryos and oocytes to be subject to import control procedures' in the questionnaire on CBPP status in Chapter 1.6.

The revised questionnaire, which is presented at Annex XXIII, is provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 31. Lumpy skin disease (Chapter 11.12.)

The Code Commission received comments from Australia, the EU and an expert.

Consistent with the policy of the OIE to incorporate articles dealing with safe commodities, the Code Commission created a new Article, 11.12.1.*bis*, 'safe commodities' and included 'milk and milk products' and 'meat and meat products' in the list of safe commodities, based on the recommendation of the *ad hoc* Group on Trade in Animal Products ('commodities') (report of July 2008 meeting).

The Code Commission agreed to replace 'animals of the bovine species' with 'cattle' in Articles 11.12.2. and 11.12.3. for consistency with Articles 11.12.4. and 5. The Code Commission also modified Articles 11.12.6., 9. and 11.

The revised Chapter, which is presented at Annex XXIV, is provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 32. Equine diseases

a) African horse sickness (Chapter 12.1.)

The Code Commission reviewed the report of the *ad hoc* Group on Official Disease Status Recognition of African Horse Sickness and supported the proposed new articles, based on the recommendation of the *ad hoc* Group.

The Code Commission discussed the use of "country or zone at risk" and decided to delete all references to 'at risk' in Articles 12.1.5 and 12.1.6. because the mitigation of the risk arising from a neighbouring country or zone is addressed by a new paragraph in Article 12.1.2., similar to that found in Chapter 8.3. (Bluetongue).

The Code Commission reviewed the proposed text in Points a) and b) of Article 12.1.10. 'Protecting animals from culicoides attack'. The Commission deleted proposed text describing 'vector proof' on the basis that 'protection' against vectors is feasible in the setting of a commercial quarantine facility but that 'proofing' against vectors is typically found only in high security laboratories. Such facilities are used for the conduct of experiments with highly pathogenic and contagious agents, not for international trade in animals and animal products (such as semen).

The Code Commission introduced the concept of vector protection, which is also relevant to chapters on other vector borne diseases. The same modification was introduced in Chapter 8.3. (Bluetongue). The Code Commission agreed that relevant text in chapters on other vector borne diseases would be addressed in future.

Questionnaire on AHS free countries and zones

The Code Commission reviewed the draft questionnaire for AHS free countries and zones provided by the Scientific Commission, based on the work on an *ad hoc* Group. The International Trade Department undertook to review the references to wildlife (equidae) to ensure that they were used in a manner that was consistent with the new definition of 'wildlife' proposed for inclusion in the Glossary. The text is provided as a clean text.

EU comment

The EU can support the proposed changes but has some comments.

b) Equine influenza (Chapter 12.6.)

The Code Commission received comments from Australia and advice from the Scientific Commission on previous comments from Australia and the EU.

The Code Commission clarified that according to the proposed modified definition of wildlife, feral animals (horses, in this case) are considered as wildlife.

The Code Commission discussed the definition of equine influenza in Article 12.6.1. and agreed that, for the purposes of the *Terrestrial Code*, the disease is defined as a disease of domestic horses, donkeys and mules.

Members' comments on Article 12.6.4. were accepted and the text modified to include the words '*within and*' between 'movements of equids' and 'into the country'.

In Article 12.6.4. the Code Commission modified the text according to the Scientific Commission recommendation, to include: 'A country, zone or compartment seeking freedom from EI should apply appropriate movement controls to minimise the risk of introduction of equine influenza virus, in accordance with this chapter'.

EU comment

The EU can support the proposed changes.

c) Equine viral arteritis (Chapter 12.9.)

The Code Commission received comments from Australia and advice from the Scientific Commission on previous comments from Chile and South Africa.

Modifications were made to point 3b) Article 12.9.2., recognising that this provided for harmonisation of the text. On the advice of the Scientific Commission, the Code Commission did not accept other proposals of Members to modify text in Chapter 12.9.

EU comment

The EU can support the proposed changes.

The revised Chapters, which are presented at Annex XXV, are provided for Member comments.

Item 33. Enzootic abortion of ewes (ovine chlamydiosis) (Chapter 14.5.)

The Code Commission received comments from New Zealand.

The Code Commission addressed the comment by adopting the description of the disease found in the *Terrestrial Manual* and modifying the title of the chapter in accordance with the discussion in Part A. In addition, Article 14.5.1. was amended accordingly.

The revised Chapters, which are presented at Annex XXVI, are provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 34. Scrapie (Chapter 14.9.)

The Code Commission received comments from Argentina, Australia, the EU and the USA.

A comment from Members questioning the safety of *in vivo* derived embryos was not accepted by the Code Commission because conclusions on the safety of transferred embryos are based on recommendations from the International Embryo Transfer Society which are, in turn, based on peer reviewed studies.

The Code Commission discussed the issue of host genotype and noted the advice of the Scientific Commission 'Although there is now good scientific evidence on scrapie-resistant genotype selection available (mainly in Europe and North America), the OIE would still need more data and evidence from the

rest of the world to enable the development of global standards' . The Code Commission did not, therefore, propose any new text in the *Terrestrial Code*.

Following a Member comment, the Code Commission deleted 'accredited' in Point 3 of Article 14.9.4. because 'free establishment' is a defined term.

Two Members proposed to reintroduce a point in Article 14.9.8., point 1 regarding the safety of semen. The Code Commission rejected this proposal because it had been discussed and the text on semen removed with support of Delegates at the 78th General Session (May 2010). In addition there is no evidence that the proposed risk mitigation measure adds to the safety of semen.

A Member requested that the Code Commission provide the scientific basis for considering that the adrenal gland, pancreas and liver are not safe commodities. The reference was provided, as follows. Hadlow WJ. Kennedy RC, Race RE (1982). Natural infection of Suffolk sheep with scrapie virus. *Journal of Infectious Diseases*, 146: 657-664.

The revised Chapter, which is presented at Annex XXVII, is provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 35. Classical swine fever (Chapter 15.2.)

The Code Commission received comments from Australia and from the Scientific Commission.

Article 15.2.1. was modified for consistency with the rest of the *Terrestrial Code*.

Article 15.2.13. was modified according to a Member's comment.

Article 15.2.23. was modified to add references to surveillance relative to a compartment, taking into account that wild pigs should not be present in a free compartment.

Articles 15.2.24. and 15.2.25. were modified according to advice of the Scientific Commission.

The revised Chapter, which is presented at Annex XXVIII, is provided for Member comments.

EU comment

The EU can support the proposed changes.

Item 36. Swine vesicular disease (Chapter 15.4.)

The Code Commission received comments from the *ad hoc* Group on Swine Vesicular Disease, as supported by the Scientific Commission on previous comments from the EU, Korea (Rep. of), New Zealand and Thailand.

The Code Commission addressed Members' comments and extensively revised Chapter 15.4., taking care to align the chapter, as appropriate, with Chapter 15.2 (classical swine fever) and other disease chapters (e.g. with respect to definitions, the treatment of findings of infection in wild pigs, and the definition of zones and compartments).

On the basis that the Code Commission was not aware of the existence of international trade in live wild pigs, and consistent with the recommendation of the *ad hoc* Group, supported by the Scientific Commission, Article 15.4.8. was deleted.

The revised Chapter, which is presented at Annex XXIX, is provided for Member comments.

EU comment

The EU has very important comments that should imperatively be taken into account by the TAHSC in its next meeting.

Item 37. Report of the *ad hoc* Group on Communications

Ms Maria Zampaglione, Head of the Communication Unit, provided an update on the report of the *ad hoc* Group on Communication, which met on 30 June–2 July 2010. The *ad hoc* Group revised definitions, taking into account Member comments, and drafted new text on communication. They recommended that the draft text be included in the *Terrestrial Code* either as a new chapter or as part of an existing chapter. Ms Zampaglione highlighted the importance of institutionalising communication, as a recognised discipline, within Veterinary Services.

The Code Commission noted the report of *ad hoc* Group on Communication and proposed that the new text be included in the *Terrestrial Code* as a new chapter in Section 3. For ease of review, the new text is provided as a clean text except the section on definitions which are shown in double underline/strikeout to show changes following consideration of Member comments.

The new Chapter, which is presented at Annex XXX, is provided for Member comments. The report of the *ad hoc* Group is attached in Annex XXXV for information of Members.

EU comment

The EU supports the inclusion of this new chapter but has some comments.

Item 38. Report of the *ad hoc* Group on Veterinary Education

Dr Etienne Bonbon, who is a member of the *ad hoc* Group, made some introductory comments on the report of the June 2010 meeting. The main objective of the OIE is to raise awareness on the part of veterinary education establishments (VEE) of the competencies needed by veterinarians, at graduation, to help to ensure that the national veterinary services can meet the OIE quality standards set out in the *Terrestrial Code* Section 3. Dr Kahn informed the Code Commission that some 80% of VEEs in the world do not meet an acceptable standard of veterinary teaching. While the primary objective of the OIE is not to provide guidance to the 20% of VEEs, nonetheless it is important that on day 1 of obtaining the veterinary qualification, all individuals at least have an appreciation/awareness of the national regulatory framework, whether or not they intend to pursue a career in the public sector. The *ad hoc* Group will hold its next meeting on 15–17 December 2010. Dr Kahn explained that Members will be asked to provide their comments on the draft report by 10 December 2010 to facilitate consideration by the *ad hoc* Group. For the moment, the text is not intended for inclusion in the *Terrestrial Code*. Nonetheless, at its February 2011 meeting, the Code Commission will be asked to endorse a text for approval by OIE Delegates at the 79th OIE General Session in May 2011. The work of the OIE on veterinary education will also be presented at events held as part of the celebration of Veterinary Year 2011.

The Code Commission endorsed the work of the *ad hoc* Group, in particular the fact that the report addresses competencies rather than the content of the veterinary curriculum. Noting that, in many countries, the Veterinary Services do not have direct or regular communications with the organisations responsible for the education and licensing of veterinarians, the Code Commission strongly encouraged Delegates to make appropriate arrangements for liaison with veterinary Deans, professional veterinary associations, and the veterinary statutory body (as appropriate) in preparing comments on this report.

The Code Commission looked forward to receiving a revised draft document, addressing the comments of OIE Delegates as appropriate, at its next meeting.

The report of the *ad hoc* Group is attached in Annex XXXVI for information of Members.

EU comment

The EU supports the OIE in addressing the issue of veterinary education.

3. Other issues

Item 39. OIE work programme on standard setting for foodborne pathogens

The Code Commission received comments from Australia, Canada and New Zealand on the OIE Paper on Priorities for the Development of Animal Production Food Safety Standards. In accordance with comments of some Members, the Code Commission supported continued collaboration between the OIE, FAO and WHO (and Codex Alimentarius Commission) on standard setting for foodborne pathogens.

Dr Kahn advised that the next step would be a meeting of a new *ad hoc* Group on Parasitic Diseases, which would be asked to update the existing *Terrestrial Code* Chapters on the listed pathogens, *Echinococcus granulosus* and *Trichinella* sp., draft a new chapter on the listed pathogen, *Cysticercus Cellulosae (Taenia solium)*, and to advise on the possible future need for the OIE to provide advice (outside the *Terrestrial Code*) on the unlisted pathogen, *Cysticercus Bovis (Taenia saginata)*.

EU comment

The EU supports the OIE in addressing the issue of zoonotic parasites, and is ready to provide expertise in this field.

Item 40. Update on the OIE's work on Private standards

Dr Kahn updated members of the Code Commission on the outcomes of two meetings of the *ad hoc* Group on Private Standards (16 February and 10 September 2010). The Code Commission noted that the Group has provided advice on how to progress Resolution 26 of the 78th OIE General Session (May 2010) on the issue of private standards.

The report of the relevant meetings is attached in Annex XXXVII for information of Members.

EU comment

The EU commends the OIE initiative to discuss the matter with the private organisations and encourage both parties to find common language.

Item 41. Porcine reproductive and respiratory syndrome

The Code Commission received comments from New Zealand.

Noting that porcine reproductive and respiratory syndrome (PRRS) is the cause of trade problems and that at least one Member has conducted specific import risk analyses on PRRS in pig meat and semen, the Code Commission considered that a chapter should be developed on the disease. This request was passed to the Scientific Commission.

EU comment

The EU is ready to provide expertise in the field of PRRS.

Item 42. Future work programme of the Code Commission

Naming and ordering of diseases and disease chapters

In the context of the development of global policies on the interface between human health and animal health, including the role of wild animals, and proposed changes to the OIE requirements for notification of diseases of domestic animals and wildlife, the Code Commission saw a need to modify the list in Article 1.2.3. and restructure Volume 2 of the *Terrestrial Code* accordingly.

An appropriate option would be to restructure the list and Volume 2 according to the scientific name of the pathogen (e.g. Chapter 11.6. 'Bovine Tuberculosis' to be renamed '*M. bovis* infection...'). The International Trade Department undertook to provide a proposal for consideration by the Code Commission at its Spring 2011 meeting.

The Code Commission updated its work programme for 2010–2011, with a table showing each item, annex, chapter numbers and status, and a list of acronyms used in this report, for information of Members (Annex XXXVIII).

EU comment

The EU thanks the OIE for this work.

Item 43. Other issues

Proposal to develop a policy on the wildlife-domestic animal interface as a guideline for future standard setting by the OIE

The Code Commission noted and agreed with the overall approach, except that it considered that the responsibility for developing policy on disease reporting (in domestic and in wild animals) is with the Sanitary Information Department, in liaison with the Code Commission and the Scientific Commission.

To test the proposed approach, the Code Commission invited the Wildlife Working Group and the Scientific Commission to review Chapter 8.5. (FMD) and provide recommendations on any modification of the text that may be appropriate, for consideration of the Code Commission and Members.

Request for approval of an OIE Collaborating Centre on Animal Welfare (Sweden)

The Code Commission noted that the AWWG had supported, on technical grounds, the application from Sweden and also noted that the OIE Council was reviewing a draft policy on the approval of new OIE Reference Laboratories and Collaborating Centres. Therefore, the Code Commission took no further action on the proposal from Sweden pending advice of the Council's decision.

The next meeting of the Code Commission is scheduled for 1–10 February 2011.

.../Annexes

ITEM, ANNEX, CHAPTER NUMBERS, TITLE AND EU COMMENTS

Item	Annex	Chapter	Title	EU comments
2	III		Glossary	Support
3	IV	1.1. 1.2. 10.6. 10.7. 10.9. 10.12 15.5.	Notification of diseases and epidemiological information Criteria for listing diseases Avian tuberculosis Duck virus enteritis Fowl cholera Marek's disease Teschovirus encephalomyelitis	Support modification of 1.1. Support deletion of chapters
7	V	3.1. 3.2. new	Veterinary services Evaluation of veterinary services Veterinary legislation	Support
8	VI	4.2.	Design and implementation of systems to achieve animal traceability	Support
9	VII	4.3. 4.4.	Zoning and compartmentalisation Application of compartmentalisation	Support
10	VIII	4.6.	Collection and processing of bovine, small ruminant and porcine semen	Support
12	IX	5.2.	Certification procedures	Support
13	X	6.3.	Control of hazards of animal health and public health importance in animal feed	Support
14	XI	new	Control of OIE listed diseases in heat treated, shelf stable pet food	**Strong comments**
15	XII	6.4.	Biosecurity procedures in poultry production	Support
		6.5.	Prevention, detection and control of Salmonella in poultry	Support
17	XIII	7.3. 7.4. 7.5. 7.6. 7.7. 7.8.	Transport of animals by land Transport of animals by air Slaughter of animals Killing of animals for disease control purposes Stray dog population control Use of animals in research and education	Support but important comments
18	XIV	8.1.	Anthrax	Support but comments
19	XV	8.2.	Aujeszky's disease	Support but comments
20	XVI	8.3.	Bluetongue	**Cannot support if comments not taken**
21	XVII	8.5. 1.6.	Foot and mouth disease Questionnaire on foot and mouth disease (Article 1.6.3.)	Support but important comments
22	XVIII	8.10. 5.11.	Rabies Rabies model international veterinary certificate for domestic dogs (*Canis familiaris*), cats (*Felis catus*) and	**Support but strong comments**

			ferrets (*Mustela putorius furo*)	
23	XIX	8.15.	Vesicular stomatitis	Support
24	XX	14.4.	Hygiene and disease security procedures in apiaries	Support
		9.1. 9.2. 9.3. 9.4. 9.5. 9.6.	Acarapisosis of honey bees American foulbrood of honey bees European foulbrood of honey bees Small hive beetle infestation (Aethina tumida) Tropilae laps infestation of honey bees Varroosis of honey bees	**Support but strong comments**
25	XXI	10.4.	Avian influenza	Support
26	XXII	10.13	Newcastle disease	Support
30	XXIII	1.6.	Questionnaire on contagious bovine pleuropneumonia (Article 1.6.5.)	Support
31	XXIV	11.12	Lumpy skin disease	Support but comments
32	XXV	12.1 1.6. 12.7. 12.10	African horse sickness Questionnaire on African horse sickness (Article 1.6.6.) Equine influenza Equine viral arteritis	Support but comments Support Support
33	XXVI	14.5.	*Chlamydophila abortus* infection (enzootic abortion of ewes, ovine chlamydiosis)	Support
34	XXVII	14.9.	Scrapie	Support
35	XXVIII	15.2.	Classical swine fever	Support
36	XXIX	15.4.	Swine vesicular disease	**Cannot support if comments not taken**
37	XXX	new	Communications	Support but comments

Annex III

GLOSSARY

EU comment

The EU welcomes the work carried out by the OIE to improve the definitions of antimicrobial agent and euthanasia and thanks the TAHSC for having taken on board the EU comments.

The EU can support the inclusion of the proposed new definitions, except that of "Wildlife".

For the purposes of the *Terrestrial Code*:

Antimicrobial agent

means a naturally occurring, semi-synthetic or synthetic substance that ~~at *in vivo* concentrations~~ exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms) at concentrations attainable *in vivo*. Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

Captive wild animal

means an *animal* that have a phenotype not significantly affected by human selection but that are captive or otherwise live under supervision or control by humans.

EU comment

There is a grammar mistake in the above definition: it should read "an *animal* that has~~ve~~ a phenotype not significantly affected by human selection but that is ~~are~~ captive or otherwise live~~s~~… etc"

Euthanasia

means the act of inducing *death* using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to the *animal.*

Feral animal

means a previously domestic *animal* that now live without supervision, control by or dependence on humans.

Veterinary legislation

means laws, regulations and all associated legal instruments that pertain to the veterinary domain.

Wild animal

means an *animal* that have a phenotype unaffected by human selection and live independent of direct human supervision or control.

EU comment

There is a grammar mistake in the above definition: it should read "an *animal* that has~~ve~~ a phenotype unaffected by human selection and live~~s~~… etc"

Wildlife

means any combination of *feral animals*, *captive wild animals* and *wild animals.*

EU comment

This definition adds more to confusion than it helps, because it could lead to different interpretations when the term is used in the chapters. Since there are definitions for each category of wildlife and if, as stated in the report, in all places in the Code where "wildlife" appears, it would be replaced by the correct term, this last one is unnecessary and should therefore be deleted. As the word wildlife is used elsewhere on the OIE website, it should be explained there that there is now three different precise definitions.

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Annex IV

CHAPTER 1.1.

NOTIFICATION OF DISEASES AND EPIDEMIOLOGICAL INFORMATION

EU comment

The EU can support the proposed changes, but has two comments.

Article 1.1.1.

For the purposes of the *Terrestrial Code* and in terms of Articles 5, 9 and 10 of the OIE Organic Statutes, ~~every~~ OIE Member ~~of the organisation~~ shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its territory or territories.

All *notifications* and all information sent by the OIE to the *Veterinary Authority* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to the OIE by the *Veterinary Authority* shall be regarded as having been sent by the country concerned.

Article 1.1.2.

1. Members shall make available to other Members, through the OIE, whatever information is necessary to minimise the spread of important animal *diseases* and to assist in achieving better worldwide control of these *diseases*.

2. To achieve this, Members shall comply with the *notification* requirements specified in Article 1.1.3.

3. To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the official OIE *disease* reporting format.

4. Recognising that scientific knowledge concerning the relationship between disease agents and *diseases* is constantly developing and that the presence of an infectious agent does not necessarily imply the presence of a *disease*, Members shall ensure through their reports that they comply with the spirit and intention of point 1 above.

5. In addition to notifying new findings in accordance with Article 1.1.3., Members shall also provide information on the measures taken to prevent the spread of *diseases*; including quarantine measures and restrictions on the movement of *animals*, animal products and biological products and other miscellaneous objects which could by their nature be responsible for transmission of *disease*. In the case of *diseases* transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

Article 1.1.3.

Veterinary Authorities shall, under the responsibility of the national Delegate, send to the *Headquarters*:

EU comment

The EU proposes to delete the word "national" as it is obvious that the Delegate, according to OIE Rules is mandated by his/her national Government.

1. in accordance with relevant provisions in the disease specific chapters, *notification* ~~from the national Delegate to the OIE~~ by telegram, fax or e-mail, within 24 hours, of any of the following events:

EU comment

Since the notification is now widely done through the WAHIS system, the EU proposes to add the words "through WAHIS or" between "*notification*" and "by telegram".

   a. first occurrence of a *listed disease* and/or *infection* in a country, a *zone* or a *compartment*;

   b. re-occurrence of a *listed disease* and/or *infection* in a country, a *zone* or a *compartment* following a report declared the *outbreak* ended;

   c. first occurrence of a new strain of a pathogen of an OIE *listed disease* in a country, a *zone* or a *compartment*;

   d. a sudden and unexpected increase in the distribution, incidence, morbidity or mortality of a *listed disease* prevalent within a country, a *zone* or a *compartment*;

   e. an *emerging disease* with significant morbidity or mortality, or zoonotic potential;

   f. evidence of change in the epidemiology of a *listed disease* (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;

2. weekly reports by telegram, fax or e-mail subsequent to a *notification* under point 1 above, to provide further information on the evolution of an incident which justified urgent *notification*; these reports should continue until the situation has been resolved through either the *disease* being eradicated or it becoming endemic so that six-monthly reporting under point 3 will satisfy the obligation of the Member to the OIE; in any case, a final report on the incident should be submitted;

3. a six-monthly report on the absence or presence, and evolution of *listed diseases* ~~*listed by the OIE*~~ and information of epidemiological significance to other Members;

4. an annual report concerning any other information of significance to other Members.

Article 1.1.4.

1. The *Veterinary Authority* of a territory in which an *infected zone* was located shall inform the *Headquarters* when this zone is free from the *disease*.

2. An *infected zone* for a particular *disease* shall be considered as such until a period exceeding the *infective period* specified in the *Terrestrial Code* has elapsed after the last reported *case*, and when full prophylactic and appropriate animal health measures have been applied to prevent possible reappearance or spread of the *disease*. These measures will be found in detail in the various chapters of Volume 2 of the *Terrestrial Code*.

3. A Member may be considered to regain freedom from a specific *disease* when all conditions given in the relevant chapters of the *Terrestrial Code* have been fulfilled.

4. The *Veterinary Authority* of a Member which sets up one or several *free zones* shall inform the OIE giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the *zones* on a map of the territory of the Member.

Article 1.1.5.

1. The *Headquarters* shall send by telegram, fax, e-mail or *Disease Information* to the *Veterinary Authorities* concerned, all *notifications* received as provided in Articles 1.1.2. to 1.1.4.

2. The *Headquarters* shall dispatch to the Delegates information on new *outbreaks* of *listed diseases*.

3. The *Headquarters*, on the basis of information received and of any official communication, shall prepare an annual report concerning the application of the *Terrestrial Code* and its effects on *international trade*.

Article 1.1.6.

~~All t~~Telegrams or faxes sent by *Veterinary Authorities* in pursuance of Articles 1.1.3. and 1.1.5. shall receive priority in accordance with the circumstances. Communications by telephone, telegram or fax, sent in the case of exceptional urgency when there is danger of spread of a notifiable epizootic *disease*, shall be given the highest priority accorded to these communications by the International Arrangements of Telecommunications.

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Annex IV (contd)

CHAPTER 1.2.

CRITERIA FOR LISTING DISEASES

EU comment

The EU can support the proposed changes of chapter 1.2 and the proposed deletion of chapters 10.6, 10.7, 10.9, 10.12 and 15.5.

The EU wishes that before proposing any change to the decision tree, the OIE TAHSC works on a clear description of its proposition. The report of the ad hoc group on listing of diseases does not use the current version to be modified, and does not explain enough the rationale for the changes, so it is difficult to make relevant comments.

In order to help countries wishing information on the delisted diseases, the EU encourages the OIE to keep or create if possible technical disease cards.

Article 1.2.1.

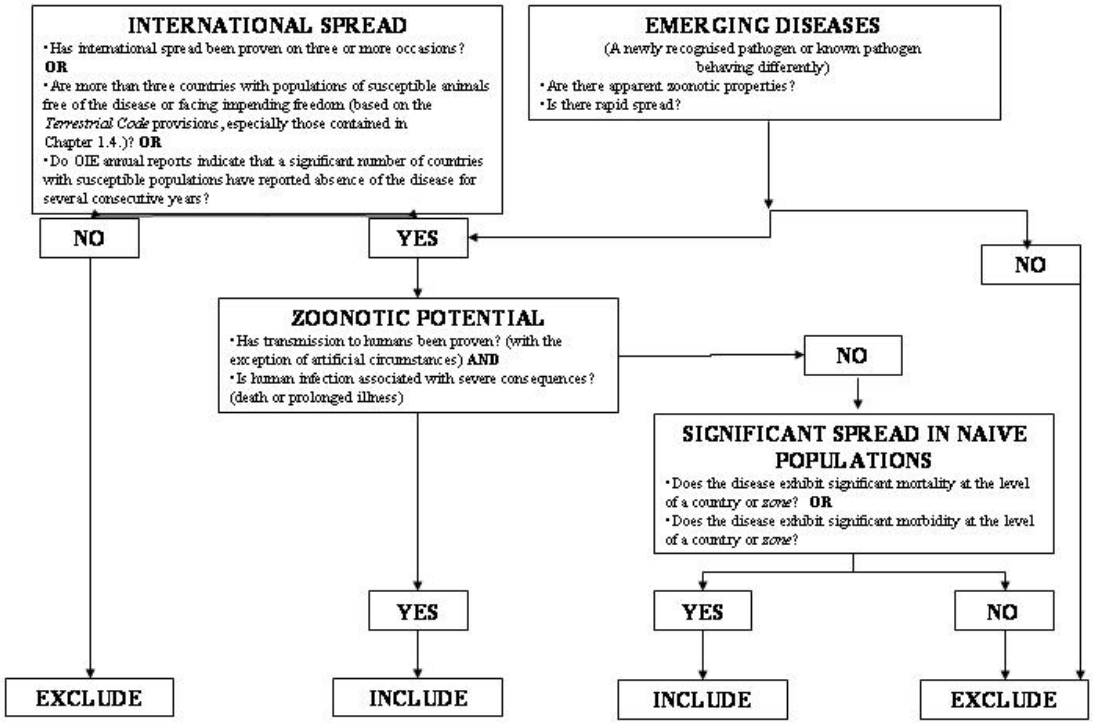
The criteria for the inclusion of a *disease* in the OIE List are as follows:

Basic criteria	**Parameters (at least one 'yes' answer means that the criterion has been met)**
International Spread	Has international spread been proven on three or more occasions? **OR** Are more than three countries with populations of susceptible animals free of the *disease* or facing impending freedom (based on the relevant provisions of the *Terrestrial Code*, and in particular those contained in Chapter 1.4.)? **OR** Do OIE annual reports indicate that a significant number of countries with susceptible populations have reported absence of the *disease* for several consecutive years?
Zoonotic Potential	Has transmission to humans been proven? (with the exception of artificial circumstances) **AND** Is human infection associated with severe consequences? (death or prolonged illness)
Significant Spread within Naïve Populations	Does the *disease* exhibit significant mortality at the level of a country or a *zone*? **OR** Does the *disease* exhibit significant morbidity at the level of a country or a *zone*?

Emerging Diseases	Are there apparent zoonotic properties or is there a rapid spread?

Article 1.2.2.

The criteria in Article 1.2.1. above are applied according to the decision-making model shown below:



Article 1.2.3.

The following *diseases* are included in the OIE List.

In case of modifications of this list of animal *diseases* adopted by the General Assembly, the new list comes into force on 1 January of the following year.

1. The following *diseases* are included within the category of multiple species *diseases*:

   - Anthrax
   - Aujeszky's disease

- Bluetongue
- Brucellosis (*Brucella abortus*)
- Brucellosis (*Brucella melitensis*)
- Brucellosis (*Brucella suis*)
- Crimean Congo haemorrhagic fever
- Echinococcosis/hydatidosis
- Epizootic haemorrhagic disease
- Equine encephalomyelitis (Eastern)
- Foot and mouth disease
- Heartwater
- Japanese encephalitis
- ~~Leptospirosis~~
- New world screwworm (*Cochliomyia hominivorax*)
- Old world screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Rabies
- Rift Valley fever
- Rinderpest
- Surra (*Trypanosoma evansi*)
- Trichinellosis
- Tularemia
- Vesicular stomatitis
- West Nile fever.

2. The following *diseases* are included within the category of cattle *diseases*:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy

- Bovine tuberculosis
- Bovine viral diarrhoea
- Contagious bovine pleuropneumonia
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Lumpy skin disease
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted).

3. The following *diseases* are included within the category of sheep and goat *diseases*:

- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Enzootic abortion of ewes (ovine chlamydiosis)
- Maedi–visna
- Nairobi sheep disease
- Ovine epididymitis (*Brucella ovis*)
- Peste des petits ruminants
- Salmonellosis (S. abortusovis)
- Scrapie
- Sheep pox and goat pox.

4. The following *diseases* are included within the category of equine *diseases*:

- African horse sickness
- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Western)
- Equine infecti-us anaemia
- Equine influenza
- Equine piroplasmosis

- Equine rhinopneumonitis
- Equine viral arteritis
- Glanders
- Venezuelan equine encephalomyelitis.

5. The following *diseases* are included within the category of swine *diseases*:

- African swine fever
- Classical swine fever
- Nipah virus encephalitis
- Porcine cysticercosis
- Porcine reproductive and respiratory syndrome
- Swine vesicular disease
- ~~Teschovirus encephalomyelitis (under study)~~
- Transmissible gastroenteritis.

6. The following *diseases* are included within the category of avian *diseases*:

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (Mycoplasma gallisepticum)
- Avian mycoplasmosis (Mycoplasma synoviae)
- Duck virus hepatitis
- ~~Fowl cholera~~
- Fowl typhoid
- Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry as defined in Chapter 10.4.
- Infectious bursal disease (Gumboro disease)
- ~~Marek's disease~~
- Newcastle disease
- Pullorum disease
- Turkey rhinotracheitis.

7. The following *diseases* are included within the category of lagomorph *diseases*:

- Myxomatosis
- Rabbit haemorrhagic disease.

8. The following *diseases* are included within the category of bee *diseases*:

- Acarapisosis of honey bees
- American foulbrood of honey bees
- European foulbrood of honey bees
- Small hive beetle infestation (*Aethina tumida*)
- *Tropilaelaps* infestation of honey bees
- Varroosis of honey bees.

9. The following *diseases* are included within the category of other *diseases*:

- Camelpox
- Chronic wasting disease
- Leishmaniosis.

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Annex IV (contd)

CHAPTER 10.6.

AVIAN TUBERCULOSIS

Article 10.6.1.

General provisions

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 10.6.2.

Recommendations for the importation of birds for breeding or rearing

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of avian tuberculosis on the day of shipment;

2. come from *establishments* which are regularly inspected by the *Veterinary Authority* and which are recognised as being free from avian tuberculosis.

Article 10.6.3.

Recommendations for the importation of birds for slaughter

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of avian tuberculosis on the day of shipment;

2. come from *establishments* which are regularly inspected by the *Veterinary Authority* and are recognised as being free from avian tuberculosis; or

3. come from *establishments* in which no *case* of avian tuberculosis has been reported;

4. are not being eliminated as part of an eradication programme against avian tuberculosis.

Article 10.6.4.

Recommendations for the importation of wild avian species destined for zoological gardens

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that prior to shipment, the birds showed no clinical sign of avian tuberculosis and, as far as can be determined, had not been exposed to avian tuberculosis.~~

~~Article 10.6.5.~~

~~**Recommendations for the importation of hatching eggs**~~

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:~~

~~1. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;~~

~~2. come from *establishments* and/or hatcheries which are recognised as being free from avian tuberculosis;~~

~~3. were shipped in clean and unused packages.~~

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Annex IV (contd)

CHAPTER 10.7.

DUCK VIRUS ENTERITIS

Article 10.7.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for duck virus enteritis (DVE) shall be 7 days (chronic carriers occur).

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 10.7.2.

Recommendations for the importation of ducks

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of DVE on the day of shipment;
2. come from *establishments* which are regularly inspected by the *Veterinary Authority*;
3. come from *establishments* which are recognised as being free from DVE;
4. have not been vaccinated against DVE; or
5. were vaccinated against DVE (the nature of the vaccine used and the date of vaccination should also be stated in the *certificate*).

Article 10.7.3.

Recommendations for the importation of day-old ducks

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;
2. have not been vaccinated against DVE; or

3. were vaccinated against DVE (the nature of the vaccine used and the date of vaccination should also be stated in the *certificate*);

4. are the progeny of parent *flocks* which:

   a. come from *establishments* and/or hatcheries which are recognised as being free from DVE;

   b. come from *establishments* and/or hatcheries in which vaccination against DVE is not practised on the parent stock; or

   c. come from *establishments* and/or hatcheries in which vaccination against DVE is practised on the parent stock;

5. were shipped in clean and unused packages.

Article 10.7.4.

Recommendations for the importation of hatching eggs of ducks

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. have been disinfected in conformity with the standards referred to in Chapter 6.4.;

2. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;

3. were shipped in clean and unused packages.

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— text deleted

Annex IV (contd)

CHAPTER 10.9.

FOWL CHOLERA

Article 10.9.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for fowl cholera (FC) shall be 14 days (chronic carriers occur).

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 10.9.2.

Recommendations for the importation of domestic birds

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of FC on the day of shipment;
2. come from *establishments* which are regularly inspected by the *Veterinary Authority*;
3. come from *establishments* which are recognised as being free from FC;
4. have not been vaccinated against FC; or
5. were vaccinated against FC (the nature of the vaccine used and the date of vaccination should also be stated in the *certificate*).

Article 10.9.3.

Recommendations for the importation of day-old birds

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

1. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;
2. have not been vaccinated against FC; or

3. were vaccinated against FC (the nature of the vaccine used and the date of vaccination shall also be stated in the *certificate*);

4. are the progeny of parent *flocks* which:

   a. come from *establishments* and/or hatcheries which are recognised as being free from FC;

   b. come from *establishments* and/or hatcheries in which vaccination against FC is not practised on the parent stock; or

   c. come from *establishments* and/or hatcheries in which vaccination against FC is practised on the parent stock;

5. were shipped in clean and unused packages.

Article 10.9.4.

Recommendations for the importation of hatching eggs of domestic birds

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:

1. have been disinfected in conformity with the standards referred to in Chapter 6.4.;

2. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;

3. were shipped in clean and unused packages.

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— text deleted

Annex IV (contd)

CHAPTER 10.12.

MAREK'S DISEASE

Article 10.12.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for Marek's disease (MD) shall be 4 months.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 10.12.2.

Recommendations for the importation of chickens

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the birds:

1. showed no clinical sign of Marek's disease on the day of shipment;
2. come from an *establishment* which is regularly inspected by the *Veterinary Authority*;
3. have not been vaccinated against MD and come from an *establishment* which has been free from MD for at least the past 2 years; or
4. were vaccinated against MD (the nature of the vaccine used and the date of vaccination should also be stated in the *certificate*).

Article 10.12.3.

Recommendations for the importation of day-old birds

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *day old birds*:

1. come from *establishments* which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Chapter 6.4.;
2. were vaccinated against MD (the nature of the vaccine used and the date of vaccination should also be stated in the *certificate*);
3. were shipped in clean and unused packages.

~~Article 10.12.4.~~

~~**Recommendations for the importation of hatching eggs of chickens**~~

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:~~

~~1. have been disinfected in conformity with the standards referred to in Chapter 6.4.;~~

~~2. come from *establishments* which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Chapter 6.4.;~~

~~3. come from *establishments* in which vaccination against MD is practised (the nature of the vaccine used and the date of vaccination should also be stated in the *certificate*);~~

~~4. were shipped in clean and unused packages.~~

~~Article 10.12.5.~~

~~**Recommendations for the importation of meat meals and feather meals**~~

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to ensure the destruction of the MD virus.~~

~~Article 10.12.6.~~

~~**Recommendations for the importation of feathers and down**~~

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the MD virus.~~

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Annex IV (contd)

CHAPTER 15.5.

TESCHOVIRUS ENCEPHALOMYELITIS (PREVIOUSLY ENTEROVIRUS ENCEPHALOMYELITIS,TESCHEN DISEASE,TALFAN DISEASE) (UNDER STUDY)

Article 15.5.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for teschovirus encephalomyelitis shall be 40 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 15.5.2.

Teschovirus encephalomyelitis free country

A country may be considered free from teschovirus encephalomyelitis when it has been shown that teschovirus encephalomyelitis has not been present for at least the past 3 years.

This period shall be 6 months after the *slaughter* of the last affected *animal* for countries in which a *stamping out policy* is practised with or without vaccination against teschovirus encephalomyelitis.

Article 15.5.3.

Teschovirus encephalomyelitis infected zone

A *zone* shall be considered as infected with teschovirus encephalomyelitis until:

1. at least 40 days have elapsed after the confirmation of the last *case* and the completion of a *stamping out policy* and *disinfection* procedures, or

2. 6 months have elapsed after the clinical recovery or *death* of the last affected *animal* if a *stamping out policy* was not practised.

Article 15.5.4.

Recommendations for importation from teschovirus encephalomyelitis free countries

for domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of teschovirus encephalomyelitis on the day of shipment;

2. were kept in a country free from teschovirus encephalomyelitis since birth or for at least the past 40 days.

Article 15.5.5.

Recommendations for importation from teschovirus encephalomyelitis free countries

for wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of teschovirus encephalomyelitis on the day of shipment;

2. come from a country free from teschovirus encephalomyelitis;

if the country of origin has a common border with a country considered infected with teschovirus encephalomyelitis:

3. were kept in a *quarantine station* for the 40 days prior to shipment.

Article 15.5.6.

Recommendations for importation from countries considered infected with teschovirus encephalomyelitis

for domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of teschovirus encephalomyelitis on the day of shipment;

2. were kept since birth, or for the past 40 days, in an *establishment* where no *case* of teschovirus encephalomyelitis was officially reported during that period, and that the *establishment* of origin was not situated in a teschovirus encephalomyelitis *infected zone*; or

3. were kept in a *quarantine station* for the 40 days prior to shipment;

4. have not been vaccinated against teschovirus encephalomyelitis; or

Annex IV (contd)

5. were vaccinated against teschovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).

Article 15.5.7.

Recommendations for importation from countries considered infected with teschovirus encephalomyelitis

for wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of teschovirus encephalomyelitis on the day of shipment;

2. were kept in a *quarantine station* for the 40 days prior to shipment;

3. have not been vaccinated against teschovirus encephalomyelitis; or

4. were vaccinated against teschovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).

Article 15.5.8.

Recommendations for importation from teschovirus encephalomyelitis free countries

for semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *animals*:

1. showed no clinical sign of teschovirus encephalomyelitis on the day of collection of the semen;

2. were kept in a country free from teschovirus encephalomyelitis for not less than 40 days prior to collection.

Article 15.5.9.

Recommendations for importation from countries considered infected with teschovirus encephalomyelitis

for semen of pigs

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor *animals*:~~

~~1. showed no clinical sign of teschovirus encephalomyelitis on the day of collection of the semen;~~

~~2. were kept in the *exporting country*, for the 40 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of teschovirus encephalomyelitis was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in a teschovirus encephalomyelitis *infected zone*.~~

~~Article 15.5.10.~~

~~**Recommendations for importation from teschovirus encephalomyelitis free countries**~~

~~for fresh meat of pigs~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *animals*:~~

~~1. which have been kept in a country free from teschovirus encephalomyelitis since birth or for at least the past 40 days;~~

~~2. which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for teschovirus encephalomyelitis with favourable results.~~

~~Article 15.5.11.~~

~~**Recommendations for importation from countries considered infected with teschovirus encephalomyelitis**~~

~~for fresh meat of pigs~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *animals*:~~

~~1. which have not been kept in a teschovirus encephalomyelitis *infected zone*;~~

~~2. which have been slaughtered in an approved *abattoir* not situated in a teschovirus encephalomyelitis *infected zone* and have been subjected to ante-mortem and post-mortem inspections for teschovirus encephalomyelitis with favourable results.~~

~~Article 15.5.12.~~

~~**Recommendations for importation from countries considered infected with teschovirus encephalomyelitis**~~

~~for meat products of pigs~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

Annex IV (contd)

1. the entire consignment of *meat products* comes from *animals* which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for teschovirus encephalomyelitis with favourable results;
2. the *meat products* have been processed to ensure the destruction of the teschovirus encephalomyelitis virus;
3. the necessary precautions were taken after processing to avoid contact of the *meat* with any source of teschovirus encephalomyelitis virus.

Article 15.5.13.

Recommendations for importation from teschovirus encephalomyelitis free countries

for products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in a country free from teschovirus encephalomyelitis since birth or for at least the past 40 days.

Article 15.5.14.

Recommendations for importation from countries considered infected with teschovirus encephalomyelitis

for meal and flour from blood, meat, defatted bones, hooves and claws (from pigs)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to ensure the destruction of teschovirus encephalomyelitis virus.

Article 15.5.15.

Recommendations for importation from countries considered infected with teschovirus encephalomyelitis

for bristles

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of teschovirus encephalomyelitis virus, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

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Annex V

CHAPTER 3.1.

VETERINARY SERVICES

EU comment

The EU thanks the OIE TAHSC and supports the proposed changes.

Article 3.1.1.

The quality of the *Veterinary Services* depends on a set of factors, which include fundamental principles of an ethical, organisational, legislative, regulatory and technical nature. The *Veterinary Services* shall conform to these fundamental principles, regardless of the political, economic or social situation of their country.

Compliance with these fundamental principles by the *Veterinary Services* of a Member is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Members.

The same fundamental principles should apply in countries where the responsibility for establishing or applying certain animal health or welfare measures, or issuing some *international veterinary certificates* is exercised by an organisation other than the *Veterinary Services*, or by an authority or agency on behalf of the *Veterinary Services*. In all cases, the *Veterinary Services* retain ultimate responsibility for the application of these principles.

These fundamental principles are presented in Article 3.1.2. Other factors affecting quality are described in Volume 1 of the *Terrestrial Code* (notification, principles of certification, etc.).

The quality of *Veterinary Services*, including veterinary legislation ~~and regulations~~, can be measured through an evaluation, whose general principles are described in Article 3.1.3. and in Article 3.1.4.

Recommendations on the evaluation of *Veterinary Services*, including veterinary legislation, are described in Chapter 3.2.

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

Article 3.1.2.

Fundamental principles of quality

The *Veterinary Services* shall comply with the following principles to ensure the quality of their activities:

1. Professional judgement

   The personnel of *Veterinary Services* should have the relevant qualifications, scientific expertise and experience to give them the competence to make sound professional judgements.

2. Independence

   Care should be taken to ensure that *Veterinary Services*' personnel are free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.

3. Impartiality

The *Veterinary Services* should be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.

4. Integrity

The *Veterinary Services* should guarantee that the work of each of their personnel is of a consistently high level of integrity. Any fraud, corruption or falsification should be identified and corrected.

5. Objectivity

The *Veterinary Services* should at all times act in an objective, transparent and non-discriminatory manner.

6. Veterinary legislation

Veterinary legislation is prerequisite to support good governance and provide the legal framework for all key activities of the *Veterinary Services*.

Legislation should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, it should define and document the responsibilities and structure of the organisations in charge of the *animal identification system*, control of animal movements, animal disease control and reporting systems, epidemiological *surveillance* and communication of epidemiological information.

A similar demonstration should be made by *Veterinary Services* when they are in charge of veterinary public health activities.

7. General organisation

The *Veterinary Services* should be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and application of animal health and *animal welfare* measures, and of international veterinary certification activities.

The *Veterinary Services* should have at their disposal effective systems for animal disease *surveillance* and for *notification* of disease problems wherever they occur, in accordance with the provisions of the *Terrestrial Code*. Adequate coverage of animal populations should also be demonstrated. They should at all times endeavour to improve their performance in terms of animal health information systems and animal disease control.

The *Veterinary Services* should define and document the responsibilities and structure of the organisation (in particular the chain of command) in charge of issuing *international veterinary certificates*.

Each position within the *Veterinary Services* which has an impact on their quality should be described. These job descriptions should include the requirements for education, training, technical knowledge and experience.

8. Quality policy

The *Veterinary Services* should define and document their policy and objectives for, and commitment to, quality, and should ensure that this policy is understood, implemented and maintained at all levels in the organisation. Where conditions allow, they may implement a quality system corresponding to their areas of activity and appropriate for the type, range and volume of work that they have to perform. The recommendations for the quality and evaluation of *Veterinary Services* propose a suitable reference system, which should be used if a Member choose to adopt a quality system.

9. Procedures and standards

The *Veterinary Services* should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities. These procedures and standards may for example relate to:

a) programming and management of activities, including international veterinary certification activities;

b) prevention, control and notification of disease *outbreaks*;

c) *risk analysis*, epidemiological *surveillance* and zoning;

d) inspection and sampling techniques;

e) diagnostic tests for animal *diseases*;

f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of *diseases*;

g) border controls and import regulations;

h) *disinfection* and *disinfestation*;

i) treatments intended to destroy, if appropriate, pathogens in animal products.

Inasmuch as the OIE has adopted standards on these matters, the *Veterinary Services* should comply with these standards when applying animal health measures and when issuing *international veterinary certificates*.

10. Information, complaints and appeals

The *Veterinary Authority* should undertake to reply to legitimate requests from *Veterinary Authorities* of other Members or any other authority, in particular ensuring that any requests for information, complaints or appeals that they may present are dealt with in a timely manner.

A record should be maintained of all complaints and appeals and of the relevant action taken by the *Veterinary Services*.

11. Documentation

The *Veterinary Services* should have at their disposal a reliable and up-to-date documentation system suited to their activities.

12. Self-evaluation

The *Veterinary Services* should undertake periodical self-evaluation especially by documenting achievements against goals, and demonstrating the efficiency of their organisational components and resource adequacy.

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

13. Communication

Veterinary Services should have effective internal and external systems of communication covering administrative and technical staff and parties affected by their activities.

14. Human and financial resources

Responsible authorities should ensure that adequate resources are made available to implement effectively the above activities.

Article 3.1.3.

For the purposes of the *Terrestrial Code*, every Member should recognise the right of another Member to undertake, or request it to undertake, an evaluation of its *Veterinary Services* where the initiating Member is an actual or a prospective importer or exporter of *commodities* and where the evaluation is to be a component of a *risk analysis* process which is to be used to determine or review sanitary measures which apply to such trade.

Any evaluation of *Veterinary Services* should be conducted having regard to the OIE recommendations on the evaluation of *Veterinary Services* presented in Chapter 3.2.

A Member has the right to expect that the evaluation of its *Veterinary Services* will be conducted in an objective manner. A Member undertaking evaluation should be able to justify any measure taken as a consequence of its evaluation.

Article 3.1.4.

A Member which intends to conduct an evaluation of another Member's *Veterinary Services* should give them notice in writing. This notice should define the purpose of the evaluation and details of the information required.

On receipt of a formal request for information to enable an evaluation of its *Veterinary Services* by another Member, and following bilateral agreement of the evaluation process and criteria, a Member should expeditiously provide the other country with meaningful and accurate information of the type requested.

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Article 3.1.1. and in Article 3.1.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 3.1.1., prevailing in the countries concerned.

The outcome of the evaluation conducted by a Member should be provided in writing as soon as possible, and in any case within 4 months of receipt of the relevant information, to the Member which has undergone the evaluation. The evaluation report should detail any findings which affect trade prospects. The Member which conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Members over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 5.3.8.

Article 3.1.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

The OIE has established procedures for the evaluation of the *Veterinary Services* of a Member, upon request by the Member.

The World Assembly of OIE Delegates endorses a list of approved experts to facilitate the evaluation process.

Under these procedures, the Director General of the OIE recommends an expert(s) from that list.

The expert(s) facilitate(s) the evaluation of the *Veterinary Services* of the Member based on the provisions in Chapter 3.2., using the OIE *Tool for the Evaluation of Performance of Veterinary Services* (OIE *PVS Tool*).

The expert(s) produce(s) a report in consultation with the *Veterinary Services* of the Member.

The report is submitted to the Director General of the OIE and, with the consent of the Member, published by the OIE.

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Annex V (contd)

CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

EU comment

The EU can support the proposed changes but has one comment.

Article 3.2.1.

General considerations

1. Evaluation of *Veterinary Services* is an important element in the *risk analysis* process which countries may legitimately use in their policy formulations directly applying to animal health and sanitary controls of *international trade* in *animals*, animal-derived products, animal genetic material and animal feedstuffs.

   Any evaluation should be carried out with due regard for Chapter 3.1.

2. In order to ensure that objectivity is maximised in the evaluation process, it is essential for some standards of discipline to be applied. The OIE has developed these recommendations which can be practically applied to the evaluation of *Veterinary Services*. These are relevant for evaluation of the *Veterinary Services* of one country by those of another country for the purposes of *risk analysis* in *international trade*. The recommendations are also applicable for evaluation by a country of its own *Veterinary Services* – the process known as self-evaluation – and for periodic re-evaluation. These recommendations should be used by OIE experts when facilitating an evaluation under the auspices of the OIE, following a request of a Member. In applying these recommendations on the evaluation, the OIE *Tool for the Evaluation of Performance of Veterinary Services* (OIE *PVS Tool*) should be used.

   In carrying out a *risk analysis* prior to deciding the sanitary/zoosanitary conditions for the importation of a *commodity*, an *importing country* is justified in regarding its evaluation of the *Veterinary Services* of the *exporting country* as critical.

3. The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of *risk analysis* in *international trade* in *animals* and animal-derived products to which official sanitary and/or zoosanitary controls apply.

4. In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoosanitary status of *animals* and animal products. Key elements to be covered in this process include adequacy of resources, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and history of performance, including *disease* reporting.

5. Good governance is the key to competence, integrity and confidence in organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade* in *animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.

6. Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational,

administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.

7. An *importing country* has a right of assurance that information on sanitary/zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.

8. An *exporting country* is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.

9. As the *veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration/licensing of *veterinarians* and authorisation of *veterinary para-professionals* is included.

Article 3.2.2.

Scope

1. In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:

   - organisation, structure and authority of the *Veterinary Services*;
   - human resources;
   - material (including financial) resources;
   - veterinary legislation, regulatory frameworks and functional capabilities;
   - animal health, *animal welfare* and veterinary public health controls;
   - formal quality systems including quality policy;
   - performance assessment and audit programmes;
   - participation in OIE activities and compliance with OIE Members' obligations.

2. To complement the evaluation of *Veterinary Services*, the legislative and regulatory framework, the organisational structure and functioning of the *veterinary statutory body* should also be considered.

3. Article 3.2.14. outlines appropriate information requirements for:

   - self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;
   - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
   - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;
   - evaluation by third parties such as OIE PVS experts or regional organisations.

Annex V (contd)

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

1. A key element in the evaluation is the study of the organisation and structure of the official *Veterinary Services*. The *Veterinary Services* should define and set out their policy, objectives and commitment to quality systems and standards. These organisational and policy statements should be described in detail. Organisational charts and details of functional responsibilities of staff should be available for evaluation. The role and responsibility of the Chief Veterinary Officer/Veterinary Director should be clearly defined. Lines of command should also be described.

2. The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.

3. Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological *surveillance*, *disease* control, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.

4. To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.

5. The *Veterinary Authority* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and compartmentalisation are being applied. The responsibilities of the *Veterinary Authority* should be made clear in the process of evaluation of *Veterinary Services*.

6. The *Veterinary Authority* is defined in the Glossary of the *Terrestrial Code*. As some countries have some relevant roles of the *Veterinary Authority* vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these Services. Details of their roles, relationship (legal and administrative) to each other and to the *Veterinary Authority* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.

7. Similarly, where the *Veterinary Authority* has arrangements with other providers of relevant services such as universities, laboratories, information services, etc., these arrangements should also be described. For the purposes of evaluation, it is appropriate to expect that the organisational and functional standards that apply to the *Veterinary Authority* should also apply to the service providers.

Article 3.2.4.

Evaluation criteria for quality systems

1. The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the *Veterinary Services* undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.

2. Where the *Veterinary Services* undergoing evaluation make large use of formal quality systems in the delivery of their services, it is appropriate that greater emphasis be placed on the outcomes of evaluation of these quality systems than on the resource and infrastructural components of the services.

Article 3.2.5.

Evaluation criteria for human resources

1. The *Veterinary Services* should demonstrate that their human resource component includes an integral core of full-time civil service employees. This core should always include *veterinarians*. It should also include administrative officials and *veterinary para-professionals*. The human resources may also include part-time and private sector *veterinarians* and *veterinary para-professionals*. It is essential that all the above categories of personnel be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.

2. In addition to raw quantitative data on this resource base, the functions of the various categories of personnel in the *Veterinary Services* should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the *Veterinary Services* and may be relevant, for example, to the roles of *veterinarians* and *veterinary para-professionals* in field services. In this case, the evaluation should provide assurances that *disease* monitoring is being conducted by a sufficient number of qualified, experienced field *veterinarians* who are directly involved in farm visits; there should not be an over-reliance on *veterinary para-professionals* for this task.

3. Analysis of these data can be used to estimate the potential of the *Veterinary Services* to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private *veterinarians* would not provide the *Veterinary Services* with an effective epizootiological information base without legislative (e.g. compulsory reporting of *notifiable diseases*) and administrative (e.g. official animal health surveillance and reporting systems) mechanisms in place.

4. These data should be assessed in close conjunction with the other information described in this chapter. For example, a large field staff (*veterinarians* and *veterinary para-professionals*) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

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Article 3.2.6.

Evaluation criteria for material resources

1. Financial

Actual yearly budgetary information regarding the *Veterinary Services* should be available and should include the details set out in the model questionnaire outlined in Article 3.2.14. Information is required on conditions of service for veterinary staff (including salaries and incentives), and should provide a comparison with the private sector and perhaps with other professionals. Information should also be available on non-government sources of revenue available to *veterinarians* in their official responsibilities.

2. Administrative

a. Accommodation

The *Veterinary Services* should be accommodated in premises suitable for efficient performance of their functions. The component parts of the *Veterinary Services* should be located as closely as possible to each other at the central level, and in the regions where they are represented, in order to facilitate efficient internal communication and function.

b. Communications

The *Veterinary Services* should be able to demonstrate that they have reliable access to effective communications systems, especially for animal health surveillance and control programmes. Inadequate communications systems within the field services components of these programmes or between outlying offices and headquarters, or between the *Veterinary Services* and other relevant administrative and professional services, signify an inherent weakness in these programmes. Adequate communications systems between laboratories and between field and laboratory components of the *Veterinary Services* should also be demonstrated.

Examples of types of communications which should be routinely available on an adequate country-wide basis are national postal, freight and telephone networks. Rapid courier services, facsimile and electronic data interchange systems (e.g. e-mail and Internet services) are examples of useful communication services which, if available, can supplement or replace the others. A means for rapid international communication should be available to the *Veterinary Authority*, to permit reporting of changes in national disease status consistent with OIE recommendations and to allow bilateral contact on urgent matters with counterpart *Veterinary Authorities* in trading-partner countries.

c. Transport systems

The availability of sufficient reliable transport facilities is essential for the performance of many functions of *Veterinary Services*. This applies particularly to the field services components of animal health activities (e.g. emergency response visits). Otherwise, the *Veterinary Services* cannot assure counterpart services in other countries that they are in control of the animal health situation within the country.

Appropriate means of transport are also vital for the satisfactory receipt of samples to be tested at veterinary laboratories, for inspection of imports and exports, and for the performance of *animals* and animal product inspection in outlying production or processing establishments.

3. Technical

Details available on laboratories should include resources data, programmes under way as well as those recently completed and review reports on the role or functions of the laboratory. Information as described in the model questionnaire should be used in the evaluation of laboratory services.

a. Cold chain for laboratory samples and veterinary medicines

Adequate refrigeration and freezing systems should be available and should be used throughout the country to provide suitable low temperature protection for laboratory samples in transit or awaiting analysis, as well as veterinary medical products (e.g. vaccines) when these are required for use in animal disease control programmes. If these assurances cannot be given, it may be valid to discount many types of test results, as well as the effectiveness of certain disease control programmes and the export inspection system in the country undergoing evaluation.

b. Diagnostic laboratories

Analysis of the laboratory service component of *Veterinary Services*, which would include official governmental laboratories and other laboratories accredited by the *Veterinary Services* for specified purposes, is an essential element of the evaluation process. The quality of the veterinary diagnostic laboratories of a country underpins the whole control and certification processes of the zoosanitary/sanitary status of exported *animals* and animal products, and therefore these laboratories should be subject to rigid quality assurance procedures and should use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency. An example is the use of International Standard Sera for standardising reagents.

This emphasis is valid whether one relates it to the actual testing performed on individual export consignments or to the more broad and ongoing testing regimes which are used to determine the animal health and veterinary public health profiles of the country and to support its disease control programmes. For the purposes of evaluation, veterinary diagnostic laboratories include those which are concerned with either animal health or veterinary public health activities. The *Veterinary Services* should approve and designate these laboratories for such purposes and have them audited regularly.

c. Research

The scope of animal disease and veterinary public health problems in the country concerned, the stages reached in the controls which address those problems and their relative importance can be measured to some degree by analysis of information on government priorities and programmes for research in animal health. This information should be accessible for evaluation purposes.

Article 3.2.7.

Legislation and functional capabilities

1. Animal health, animal welfare and veterinary public health

The *Veterinary Authority* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise control over all animal health matters. These controls should include, where appropriate, compulsory notification of prescribed animal diseases, inspection, movement controls through systems which provide adequate traceability, registration of facilities,

Annex V (contd)

quarantine of infected premises/areas, testing, treatment, destruction of infected *animals* or contaminated materials, controls over the use of veterinary medicines, etc. The scope of the legislative controls should include domestic *animals* and their reproductive material, animal products, wildlife as it relates to the transmission of *diseases* to humans and domestic *animals*, and other products subject to veterinary inspection. Arrangements should exist for co-operation with the *Veterinary Authorities* of the neighbouring countries for the control of animal *diseases* in border areas and for establishing linkages to recognise and regulate transboundary activities. Within the structure of *Veterinary Services*, there should be appropriately qualified personnel whose responsibilities include *animal welfare*. Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may be also considered in the evaluation.

2. Export/import inspection

The *Veterinary Authority* should have appropriate legislation and adequate capabilities to prescribe the methods for control and to exercise systematic control over the import and export processes of *animals* and animal products in so far as this control relates to sanitary and zoosanitary matters. The evaluation should also involve the consideration of administrative instructions to ensure the enforcement of *importing country* requirements during the pre-export period.

In the context of production for export of foodstuffs of animal origin, the *Veterinary Authority* should demonstrate that comprehensive legislative provisions are available for the oversight by the relevant authorities of the hygienic process and to support official inspection systems of these *commodities* which function to standards consistent with or equivalent to relevant Codex Alimentarius and OIE standards.

Control systems should be in place which permit the exporting *Veterinary Authority* to approve export premises. The *Veterinary Services* should also be able to conduct testing and treatment as well as to exercise controls over the movement, handling and storage of exports and to make inspections at any stage of the export process. The product scope of this export legislation should include, *inter alia*, *animals* and animal products (including animal semen, ova and embryos), and animal feedstuffs.

The *Veterinary Authority* should be able to demonstrate that they have adequate capabilities and legislative support for zoosanitary control of imports and transit of *animals*, animal products and other materials which may introduce animal *diseases*. This could be necessary to support claims by the *Veterinary Services* that the animal health status of the country is suitably stable, and that cross-contamination of exports from imports of unknown or less favourable zoosanitary status is unlikely. The same considerations should apply in respect of veterinary control of public health. The *Veterinary Services* should be able to demonstrate that there is no conflict of interest when certifying veterinarians are performing official duties.

Legislation should also provide the right to deny and/or withdraw official certification. Penalty provisions applying to malpractice on the part of certifying officials should be included.

The *Veterinary Services* should demonstrate that they are capable of providing accurate and valid certification for exports of *animals* and animal products, based on Chapters 5.1. and 5.2. of the *Terrestrial Code*. They should have appropriately organised procedures which ensure that sanitary/animal health certificates are issued by efficient and secure methods. The documentation control system should be able to correlate reliably the certification details with the relevant export consignments and with any inspections to which the consignments were subjected.

Security in the export certification process, including electronic documentation transfer, is important. A system of independent compliance review is desirable, to safeguard against fraud in certification by officials and by private individuals or corporations. The certifying veterinarian should have no conflict of interest in the commercial aspects of the *animals* or animal product being certified and be independent from the commercial parties.

Article 3.2.8.

Animal health controls

1. Animal health status

An updated assessment of the present animal disease status of a country is an important and necessary procedure. For this undertaking, studies of the OIE publications such as *World Animal Health*, the *Bulletin* and *Disease Information* should be fundamental reference points. The evaluation should consider the recent history of the compliance of the country with its obligations regarding international notification of animal *diseases*. In the case of an OIE Member, failure to provide the necessary animal health reports consistent with OIE requirements will detract from the overall outcome of the evaluation of the country.

An *exporting country* should be able to provide further, detailed elaboration of any elements of its animal disease status as reported to the OIE. This additional information will have particular importance in the case of animal *diseases* which are foreign to or strictly controlled in the *importing country* or region. The ability of the *Veterinary Services* to substantiate elements of their animal disease status reports with surveillance data, results of monitoring programmes and details of disease history is highly relevant to the evaluation. In the case of evaluation of the *Veterinary Services* of an *exporting country* for *international trade* purposes, an *importing country* should be able to demonstrate the reasonableness of its request and expectations in this process.

2. Animal health control

Details of current animal disease control programmes should be considered in the evaluation. These programmes would include epidemiological surveillance, official government-administered or officially-endorsed, industry-administered control or eradication programmes for specific *diseases* or *disease* complexes, and animal disease emergency preparedness. Details should include enabling legislation, programme plans for epidemiological surveillance and animal disease emergency responses, quarantine arrangements for infected and exposed animals or *herds*, compensation provisions for animal owners affected by disease control measures, training programmes, physical and other barriers between the free country or zone and those infected, incidence and prevalence data, resource commitments, interim results and programme review reports.

3. National animal disease reporting systems

The presence of a functional animal disease reporting system which covers all agricultural regions of the country and all veterinary administrative control areas should be demonstrated.

An acceptable variation would be the application of this principle to specific zones of the country. In this case also, the animal disease reporting system should cover each of these zones. Other factors should come to bear on this situation, e.g. the ability to satisfy trading partners that sound animal health controls exist to prevent the introduction of *disease* or export products from regions of lesser veterinary control.

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Article 3.2.9.

Veterinary public health controls

1. Food hygiene

The *Veterinary Authority* should be able to demonstrate effective responsibility for the veterinary public health programmes relating to the production and processing of animal products. If the *Veterinary Authority* does not exercise responsibility over these programmes, the evaluation should include a comprehensive review of the role and relationship of the organisations (national, state/provincial, and municipal) which are involved. In such a case, the evaluation should consider whether the *Veterinary Authority* can provide guarantees of responsibility for an effective control of the sanitary status of animal products throughout the *slaughter*, processing, transport and storage periods.

2. Zoonoses

Within the structure of *Veterinary Services*, there should be appropriately qualified personnel whose responsibilities include the monitoring and control of zoonotic diseases and, where appropriate, liaison with medical authorities.

3. Chemical residue testing programmes

Adequacy of controls over chemical residues in exported *animals*, animal products and feedstuffs should be demonstrated. Statistically-based *surveillance* and monitoring programmes for environmental and other chemical contaminants in *animals*, in animal-derived foodstuffs and in animal feedstuffs should be favourably noted. These programmes should be coordinated nationwide. Correlated results should be freely available on request to existing and prospective trading partner countries. Analytical methods and result reporting should be consistent with internationally recognised standards. If official responsibility for these programmes does not rest with the *Veterinary Services*, there should be appropriate provision to ensure that the results of such programmes are made available to the *Veterinary Services* for assessment. This process should be consistent with the standards set by the Codex Alimentarius Commission or with alternative requirements set by the *importing country* where the latter are scientifically justified.

4. Veterinary medicines

It should be acknowledged that primary control over veterinary medicinal products may not rest with the *Veterinary Authority* in some countries, owing to differences between governments in the division of legislative responsibilities. However, for the purpose of evaluation, the *Veterinary Authority* should be able to demonstrate the existence of effective controls (including nationwide consistency of application) over the manufacture, importation, export, registration, supply, sale and use of veterinary medicines, biologicals and diagnostic reagents, whatever their origin. The control of veterinary medicines has direct relevance to the areas of animal health and public health.

In the animal health sphere, this has particular application to biological products. Inadequate controls on the registration and use of biological products leave the *Veterinary Services* open to challenge over the quality of animal disease control programmes and over safeguards against *animal disease* introduction in imported veterinary biological products.

It is valid, for evaluation purposes, to seek assurances of effective government controls over veterinary medicines in so far as these relate to the public health risks associated with residues of these chemicals in *animals* and animal-derived foodstuffs. This process should be consistent with the standards set by the Codex Alimentarius Commission or with alternative requirements set by the *importing country* where the latter are scientifically justified.

5. Integration between animal health controls and veterinary public health

The existence of any organised programme which incorporates a structured system of information feedback from inspection in establishments producing products of animal origin, in particular *meat* or dairy products, and applies this in animal health control should be favourably noted. Such programmes should be integrated within a national disease surveillance scheme.

Veterinary Services which direct a significant element of their animal health programmes specifically towards minimising microbial and chemical contamination of animal-derived products in the human food chain should receive favourable recognition in the evaluation. There should be evident linkage between these programmes and the official control of veterinary medicines and relevant agricultural chemicals.

Article 3.2.10.

Performance assessment and audit programmes

1. Strategic plans

The objectives and priorities of the *Veterinary Services* can be well evaluated if there is a published official strategic plan which is regularly updated. Understanding of functional activities is enhanced if an operational plan is maintained within the context of the strategic plan. The strategic and operational plans, if these exist, should be included in the evaluation.

Veterinary Services which use strategic and operational plans may be better able to demonstrate effective management than countries without such plans.

2. Performance assessment

If a strategic plan is used, it is desirable to have a process which allows the organisation to assess its own performance against its objectives. Performance indicators and the outcomes of any review to measure achievements against pre-determined performance indicators should be available for evaluation. The results should be considered in the evaluation process.

3. Compliance

Matters which can compromise compliance and adversely affect a favourable evaluation include instances of inaccurate or misleading official certification, evidence of fraud, corruption, or interference by higher political levels in international veterinary certification, and lack of resources and poor infrastructure.

It is desirable that the *Veterinary Services* contain (or have a formal linkage with) an independent internal unit/section/commission the function of which is to critically scrutinise their operations. The aim of this unit should be to ensure consistent and high integrity in the work of the individual officials in the *Veterinary Services* and of the corporate body itself. The existence of such a body can be important to the establishment of international confidence in the *Veterinary Services*.

An important feature when demonstrating the integrity of the *Veterinary Services* is their ability to take corrective action when miscertification, fraud or corruption has occurred.

A supplementary or an alternative process for setting performance standards and application of monitoring and audit is the implementation of formal quality systems to some or all activities for which the *Veterinary Services* are responsible. Formal accreditation to international quality system standards should be utilised if recognition in the evaluation process is to be sought.

4. Veterinary Services administration

a. Annual reports

Official government annual reports should be published, which provide information on the organisation and structure, budget, activities and contemporary performance of the *Veterinary Services*. Current and retrospective copies of such reports should be available to counterpart Services in other countries, especially trade partners.

b. Reports of government review bodies

The reports of any periodic or ad hoc government reviews of *Veterinary Services* or of particular functions or roles of the *Veterinary Services* should be considered in the evaluation process. Details of action taken as a consequence of the review should also be accessible.

c. Reports of special committees of enquiry or independent review bodies

Recent reports on the *Veterinary Services* or elements of their role or function, and details of any subsequent implementation of recommendations contained in these reports should be available. The *Veterinary Services* concerned should recognise that the provision of such information need not be detrimental to the evaluation outcome; in fact, it may demonstrate evidence of an effective audit and response programme. The supplying of such information can reinforce a commitment to transparency.

d. In-service training and development programme for staff

In order to maintain a progressive approach to meeting the needs and challenges of the changing domestic and international role of *Veterinary Services*, the national administration should have in place an organised programme which provides appropriate training across a range of subjects for relevant staff. This programme should include participation in scientific meetings of animal health organisations. Such a programme should be used in assessing the effectiveness of the Services.

e. Publications

Veterinary Services can augment their reputation by demonstrating that their staff publish scientific articles in refereed veterinary journals or other publications.

f. Formal linkages with sources of independent scientific expertise

Details of formal consultation or advisory mechanisms in place and operating between the *Veterinary Services* and local and international universities, scientific institutions or recognised veterinary organisations should be taken into consideration. These could serve to enhance the international recognition of the *Veterinary Services*.

g. Trade performance history

In the evaluation of the *Veterinary Services* of a country, it is pertinent to examine the recent history of their performance and integrity in trade dealings with other countries. Sources of such historical data may include Customs Services.

Article 3.2.11.

Participation in OIE activities

Questions on a country's adherence to its obligations as a member of the OIE are relevant to an evaluation of the *Veterinary Services* of the country. Self-acknowledged inability or repeated failure of a Member to fulfil reporting obligations to the OIE will detract from the overall outcome of the evaluation. Such countries, as well as non-member countries, will need to provide extensive information regarding their *Veterinary Services* and sanitary/zoosanitary status for evaluation purposes.

Article 3.2.12.

Evaluation of veterinary statutory body

1. Scope

In the evaluation of the *veterinary statutory body*, the following items may be considered, depending on the purpose of the evaluation:

a. objectives and functions;

b. legislative basis, autonomy and functional capacity;

c. the composition and representation of the body's membership;

d. accountability and transparency of decision-making;

e. sources and management of funding;

f. administration of training programmes and continuing professional development for *veterinarians* and *veterinary para-professionals*.

2. Evaluation of objectives and functions

The *veterinary statutory body* should define its policy and objectives, including detailed descriptions of its powers and functions such as:

a. to regulate *veterinarians* and *veterinary para-professionals* through licensing and/or registration of such persons;

b. to determine the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered as *veterinarians* and *veterinary para-professionals*;

c. to determine the standards of professional conduct of *veterinarians* and *veterinary para-professionals* and to ensure these standards are met.

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3. Evaluation of legislative basis, autonomy and functional capacity

The *veterinary statutory body* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise and enforce control over all *veterinarians* and *veterinary para-professionals*. These controls should include, where appropriate, compulsory licensing and registration, minimum standards of education (initial and continuing) for the recognition of degrees, diplomas and certificates, setting standards of professional conduct and exercising control and the application of disciplinary procedures.

The *veterinary statutory body* should be able to demonstrate autonomy from undue political and commercial interests.

Where applicable, regional agreements for the recognition of degrees, diplomas and certificates for *veterinarians* and *veterinary para-professionals* should be demonstrated.

4. Evaluation of membership representation

Detailed descriptions should be available in respect of the membership of the *veterinary statutory body* and the method and duration of appointment of members. Such information includes:

a. *veterinarians* designated by the *Veterinary Authority*, such as the Chief Veterinary Officer;

b. *veterinarians* elected by members registered by the *veterinary statutory body*;

c. *veterinarians* designated or nominated by the veterinary association(s);

d. representative(s) of veterinary para-professions;

e. representative(s) of veterinary academia;

f. representative(s) of other stakeholders from the private sector;

g. election procedures and duration of appointment;

h. qualification requirements for members.

5. Evaluation of accountability and transparency of decision-making

Detailed information should be available on disciplinary procedures regarding the conducting of enquiries into professional misconduct, transparency of decision-making, publication of findings, sentences and mechanisms for appeal.

Additional information regarding the publication at regular intervals of activity reports, lists of registered or licensed persons including deletions and additions should also be taken into consideration.

6. Evaluation of financial sources and financial management

Information regarding income and expenditure, including fee structure(s) for the licensing/registration of persons should be available.

7. Evaluation of training programmes and programmes for continuing professional development, for veterinarians and veterinary para-professionals

Descriptive summary of continuing professional development, training and education programmes should be provided, including descriptions of content, duration and participants; documented details of quality manuals and standards relating to Good Veterinary Practice should be provided.

Article 3.2.13.

1. The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.

2. A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a *risk analysis* process, which is necessary to determine the sanitary or zoosanitary measures which the country will use to protect human or animal life or health from *disease* or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.

3. In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 3.2.14. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this chapter will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study should be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country should be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 3.2.14.

This article outlines appropriate information requirements for the self-evaluation or evaluation of the *Veterinary Services* of a country.

1. Organisation and structure of Veterinary Services

   a. National Veterinary Authority

      Organisational chart including numbers, positions and numbers of vacancies.

   b. Sub-national components of the Veterinary Authority

      Organisational charts including numbers, positions and number of vacancies.

   c. Other providers of veterinary services

      Description of any linkage with other providers of veterinary services.

Annex V (contd)

2. National information on human resources

a. Veterinarians

i. Total numbers of *veterinarians* registered/licensed by the *Veterinary statutory body* of the country.

ii. Numbers of:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- private *veterinarians* authorised by the *Veterinary Services* to perform official veterinary functions *[Describe accreditation standards, responsibilities and/or limitations applying to these private veterinarians.]*;
- other *veterinarians*.

iii. Animal health:

Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area *[Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import/export and other functions, as applicable.]*:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

iv. Veterinary public health:

Numbers employed in food inspection on a majority time basis, by commodity *[Show categories and numbers to differentiate staff involved in inspection, laboratory and other functions, as applicable.]*:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

v. Numbers of veterinarians relative to certain national indices:

- per total human population;
- per farm livestock population, by geographical area;
- per livestock farming unit, by geographical area.

vi. Veterinary education:

- number of veterinary schools;
- length of veterinary course (years);
- international recognition of veterinary degree.

vii. Veterinary professional associations.

b. Graduate personnel (non-veterinary)

Details to be provided by category (including biologists, biometricians, economists, engineers, lawyers, other science graduates and others) on numbers within the *Veterinary Authority* and available to the *Veterinary Authority*.

c. *Veterinary para-professionals* employed by the *Veterinary Services*

i. Animal health:

- Categories and numbers involved with farm livestock on a majority time basis:
  - by geographical area;
  - proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.
- Education/training details.

ii. Veterinary public health:

- Categories and numbers involved in food inspection on a majority time basis:
  - *meat* inspection: export *meat* establishments with an export function and domestic *meat* establishments (no export function);
  - dairy inspection;
  - other foods.
- Numbers in import/export inspection.
- Education/training details.

d. Support personnel

Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).

e. Descriptive summary of the functions of the various categories of staff mentioned above

f. Veterinary, *veterinary para-professionals*, livestock owner, farmer and other relevant associations

g. Additional information and/or comments.

Annex V (contd)

3. Financial management information

   a. Total budgetary allocations to the *Veterinary Authority* for the current and past two fiscal years:

      i. for the national *Veterinary Authority*;

      ii. for each of any sub-national components of the *Veterinary Authority*;

      iii. for other relevant government-funded institutions.

   b. Sources of the budgetary allocations and amount:

      i. government budget;

      ii. sub-national authorities;

      iii. taxes and fines;

      iv. grants;

      v. private services.

   c. Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.

   d. Total allocation proportionate of national public sector budget. *[This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.]*

   e. Actual and proportional contribution of animal production to gross domestic product.

4. Administration details

   a. Accommodation

      Summary of the numbers and distribution of official administrative centres of the *Veterinary Services* (national and sub-national) in the country.

   b. Communications

      Summary of the forms of communication systems available to the *Veterinary Services* on a nation-wide and local area bases.

   c. Transport

      i. Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.

      ii. Details of annual funds available for maintenance and replacement of motor vehicles.

5. Laboratory services

a. Diagnostic laboratories (laboratories engaged primarily in diagnosis)

i. Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.

ii. Numbers of veterinary diagnostic laboratories operating in the country:

- government operated laboratories;

- private laboratories accredited by government for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import/export testing.

iii. Descriptive summary of accreditation procedures and standards for private *laboratories*.

iv. Human and financial resources allocated to the government veterinary *laboratories*, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.

v. List of diagnostic methodologies available against major *diseases* of farm livestock (including *poultry*).

vi. Details of collaboration with external *laboratories* including international reference laboratories and details on numbers of samples submitted.

vii. Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.

viii. Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.

ix. Details of procedures for storage and retrieval of information on specimen submission and results.

x. Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).

xi. Strategic and operational plans for the official veterinary laboratory service (if available).

b. Research laboratories (laboratories engaged primarily in research)

i. Numbers of veterinary research *laboratories* operating in the country:

- government operated *laboratories*;

- private *laboratories* involved in full time research directly related to animal health and veterinary public health matters involving production animal species.

ii. Summary of human and financial resources allocated by government to veterinary research.

iii. Published programmes of future government sponsored veterinary research.

iv. Annual reports of the government research *laboratories*.

Annex V (contd)

6. Veterinary legislation~~, regulations~~ and functional capabilities

a. Animal health and veterinary public health

i. Assessment of the adequacy and implementation of relevant legislation (national or sub-national) concerning the following:

- animal and veterinary public health controls at national frontiers;
- control of endemic animal diseases, including zoonoses;
- emergency powers for control of exotic disease outbreaks, including zoonoses;
- inspection and registration of facilities;
- animal feeding;
- veterinary public health controls of the production, processing, storage and marketing of meat for domestic consumption;
- veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods of animal origin for domestic consumption;
- registration and use of veterinary pharmaceutical products including vaccines;
- animal welfare.

ii. Assessment of ability of *Veterinary Services* to enforce legislation.

b. Export/import inspection

i. Assessment of the adequacy and implementation of relevant national legislation concerning:

- veterinary public health controls of the production, processing, storage and transportation of meat for export;
- veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other foods of animal origin for export;
- animal health and veterinary public health controls of the export and import of animals, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
- animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;
- animal health controls of importation of veterinary biological products including vaccines;
- administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);
- documentation and compliance.

ii. Assessment of ability of *Veterinary Services* to enforce legislation.

7. Animal health and veterinary public health controls

a. Animal health

i. Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.

ii. Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.

iii. Description and relevant data of current official control programmes including:

- epidemiological surveillance or monitoring programmes;

- officially approved industry administered control or eradication programmes for specific *diseases*.

iv. Description and relevant details of animal disease emergency preparedness and response plans.

v. Recent history of animal disease status:

- animal *diseases* eradicated nationally or from defined sub-national zones in the last ten years;

- animal *diseases* of which the prevalence has been controlled to a low level in the last ten years;

- animal *diseases* introduced to the country or to previously free sub national regions in the last ten years;

- *emerging diseases* in the last ten years;

- animal *diseases* of which the prevalence has increased in the last ten years.

b. Veterinary public health

i. Food hygiene

- Annual national *slaughter* statistics for the past three years according to official data by species of *animals* (bovine, ovine, porcine, caprine, *poultry*, farmed game, wild game, equine, other).

- Estimate of total annual slaughterings which occur but are not recorded under official statistics.

- Proportion of total national *slaughter* which occurs in registered export establishments, by category of *animal*.

- Proportion of total national *slaughter* which occurs under veterinary control, by category of *animal*.

- Numbers of commercial *fresh meat* establishments in the country which are registered for export by the *Veterinary Authority*:

  - *slaughterhouses* (indicate species of *animals*);

  - cutting/packing plants (indicate *meat* type);

  - *meat* processing establishments (indicate *meat* type);

  - cold stores.

- Numbers of commercial *fresh meat* establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.

- Numbers of commercial *fresh meat* establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).

- Description of the veterinary public health programme related to production and processing of animal products for human consumption (including *fresh meat*, *poultry meat*, *meat products*, game *meat*, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.

- Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the *Veterinary Authority* does not have responsibility for those programmes which apply to national production destined to domestic consumption and/or exports of the *commodities* concerned.

ii. Zoonoses

- Descriptive summary of the numbers and functions of staff of the *Veterinary Authority* involved primarily with monitoring and control of zoonotic diseases.

- Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of *zoonoses* to be provided if the *Veterinary Authority* does not have these responsibilities.

iii. Chemical residue testing programmes

- Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.

- Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.

- Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.

iv. Veterinary medicines

- Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing *animals*.

- Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.

8. Quality systems

a. Accreditation

Details and evidence of any current, formal accreditation by external agencies of the *Veterinary Services* of any components thereof.

b. Quality manuals

Documented details of the quality manuals and standards which describe the accredited quality systems of the *Veterinary Services*.

c. Audit

Details of independent (and internal) audit reports which have been undertaken of the *Veterinary Services* of components thereof.

9. Performance assessment and audit programmes

a. Strategic plans and review

i. Descriptive summary and copies of strategic and operational plans of the *Veterinary Services* organisation.

ii. Descriptive summary of corporate performance assessment programmes which relate to the strategic and operational plans - copies of recent review reports.

b. Compliance

Descriptive summary of any compliance unit which monitors the work of the *Veterinary Services* (or elements thereof).

c. Annual reports of the Veterinary Authority

Copies of official annual reports of the national (sub-national) *Veterinary Authority*.

d. Other reports

i. Copies of reports of official reviews into the function or role of the *Veterinary Services* which have been conducted within the past three years.

ii. Descriptive summary (and copy of reports if available) of subsequent action taken on recommendations made in these reviews.

Annex V (contd)

e. Training

i. Descriptive summary of in-service and development programmes provided by the *Veterinary Services* (or their parent Ministries) for relevant staff.

ii. Summary descriptions of training courses and duration.

iii. Details of staff numbers (and their function) who participated in these training courses in the last three years.

f. Publications

Bibliographical list of scientific publications by staff members of *Veterinary Services* in the past three years.

g. Sources of independent scientific expertise

List of local and international universities, scientific institutions and recognised veterinary organisations with which the *Veterinary Services* have consultation or advisory mechanisms in place.

10. Membership of the OIE

State if country is a member of the OIE and period of membership.

11. Other assessment criteria

EU comment
The EU thinks that this last point maybe very confusing. When a PVS evaluation is carried out, how would the Delegate know under which "other criteria" the services would be evaluated? This point should be deleted.

- text deleted

CHAPTER 3.3.

VETERINARY LEGISLATION

EU comment

The EU can in principle support the proposed new chapter.

Nevertheless, even if it has been on the OIE website as guidelines for some time, it is the first draft to be included in the Code and thus needs more time for a thorough study.

Moreover, the Global Conference on veterinary legislation in Djerba in December 2010 should lead to recommendations that should be validated as a resolution in May GS. As a consequence, the EU proposes that the usual pathway is followed for the adoption of this new chapter i.e. an 18 months cycle for adoption in May 2012 GS.

In any case, the EU wishes the structure of the first article be revised so that it includes a part on "General considerations" including the objectives, scope etc.

Article 3.3.1.

General principles

1. Respect of the hierarchy of Acts

   Veterinary legislation should scrupulously respect the separation between the primary legislation, represented by primary acts (laws), and the secondary legislation derived from regulations or rule books as laid down in the Constitution or fundamental texts of the country.

2. Legal basis

   The competent authorities should have the necessary primary and secondary legislation adopted for their activities at all levels of their functional or territorial organisation.

3. Inventory of the veterinary legislation

   The competent authorities should establish and maintain a complete and up to date inventory of veterinary legislation.

   The use of computerised databases is recommended, on the condition that their completeness, currency, accessibility and continuity can be guaranteed.

4. Communication

   The competent authorities should ensure communication of veterinary legislation and subsequent documentation to stakeholders.

5. Codification

   Veterinary legislation should be collected and codified so as to make it readily accessible and intelligible and provide the capability for updating and modification as appropriate.

6. Participation in the process of developing legislation

The drafting of new and updated veterinary texts should involve the competent authorities that are responsible for the scientific and technical content, together with the necessary legal expertise to ensure that the resulting texts are legally sound.

Conversely, the competent authorities should be consulted on all proposals to develop or modify texts that have a bearing on veterinary legislation.

7. Consistency of the legislation

Veterinary legislation should be consistent with civil, penal and administrative laws and the associated procedures as appropriate.

Article 3.3.2.

The form of veterinary legislation

1. Normative character

Veterinary legislation should be normative and should be drafted in a manner that prevents ambiguity in interpretation.

2. Style and precision

The syntax and vocabulary should be clear and consistent so as to avoid any ambiguity.

Precision and accuracy should take precedence over style even if this results in repetition and a cumbersome style.

3. Definitions

Definitions should refer to the precise subjects and texts to which they pertain.

Definitions in secondary legislation should not create any conflict or ambiguity with definitions in primary legislation.

4. Competent authority

The definition of 'competent authority' or 'competent authorities' should be consistent with the OIE standards in order to assure an efficient chain of command and reliability in the provision of veterinary certification.

5. Objectives of veterinary legislation

Veterinary legislation should include a clear statement of scope.

The legislation should as a minimum include relevant guidelines in order to protect:

a. animal health and food security;

b. food safety;

c. public health (zoonotic diseases) and security (stray animals);

d. animal welfare, as defined by the OIE.

6. Penalties and sanctions

Veterinary legislation should provide for penalties and sanctions at the level required for proper implementation of the overall strategy, as follows:

a. penal sanctions, to be applied by the competent jurisdictions according to current penal procedures;

b. administrative sanctions that are designed for immediate application in the case of activities posing a risk to animal health, animal welfare or public health.

Veterinary legislation should distinguish between significant penalties established in primary legislation and those less strong that depend on secondary legislation.

Veterinary legislation should include additional specific sanctions which would be applied on the basis of a decision from the court, notably a ban on the use of animals or the conduct of activities posing a risk to public or animal health or animal welfare.

7. Powers of the competent authority

Where official veterinary matters are the responsibility of more than one administration (multiple competent authorities), a reliable system of coordination and cooperation between the different authorities should be put in place.

The competent authorities should be organised in such a way as to provide for taking action quickly and coherently when such action is key to success, notably in case of implementation of animal health emergency measures or veterinary public health crises.

The legislation should provide for a chain of command that is as effective as possible (i.e. short, with all responsibilities clearly defined).

For this purpose, the responsibilities and power of the competent authorities, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined.

If they are not under the responsibility of a unique competent authority, the responsibility for each element of the public veterinary domain should be attributed to a specific competent authority.

8. Interventions by inspectors

The competent authority should appoint technically qualified inspectors to take any actions needed for implementation or verification of compliance with the veterinary legislation.

The veterinary legislation should ensure that:

a. inspectors have the legal authority to intervene in accordance with the legislation and the penal procedures in force in the State;

b. the field of competence and the role of each inspector are prescribed according to their technical qualifications;

c. inspectors are protected against legal action and physical harm.

9. Powers

The rights of inspectors should be explicitly and thoroughly listed to protect the rights of stakeholders against any abuse of authority.

The powers of inspectors and rules of inspections should be prescribed, notably the authorisation and conditions for obtaining access to professional and private premises and to vehicles.

Inspectors should have powers and procedures to:

a. gain access to documents;

b. take samples;

c. retain (set aside) animals and goods, pending a decision on final disposition.

10. Obligations

The obligation of inspectors to respect confidentiality should be defined.

When attributing a field of competence or sector of responsibility, the competent authority should respect the principles of independence and impartiality prescribed in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) (see Article 3.1.2.).

11. Administrative and enforcement actions

For the purposes of administrative and enforcement actions the following elements should be prescribed in the veterinary legislation:

a. seizure of animals, products and food of animal origin;

b. suspension of one or more activities of an inspected establishment;

c. the temporary, partial or complete closure of inspected establishments;

d. suspension or withdrawal of authorisations or approvals.

Means of compulsion enabling inspection to be performed should be provided for.

The rights of appeal against an action or a decision of an inspector should be established according to the laws of the State.

12. Financing

Veterinary legislation should provide for the sources, levels and conditions of financing required for the execution of all the activities of the competent authority, notably inspection, sampling and analysis and the procedures of authorisation or approval in all domains covered by the veterinary legislation.

Article 3.3.3.

Veterinary and para-veterinary professions

1. Veterinary medicine

In order to ensure the quality of veterinary medicine, the veterinary legislation should:

a. provide an official definition of veterinary medicine;

b. define the prerogatives of the professionals involved in the practice of veterinary medicine;

c. define the minimum initial and continuous educational requirements for the professionals;

d. prescribe the conditions for recognition of diplomas for veterinarians and para-veterinarians;

e. define the conditions for the exercise of veterinary and para-veterinary professions;

f. define the professional responsibilities of veterinarians and persons working under their control;

g. prescribe the situations where persons other than qualified veterinarians can undertake activities that are normally to be carried out by veterinarians e.g. in exceptional circumstances such as epizootics.

2. The control of the professions

In order to control the veterinary and para-veterinary professions, the veterinary legislation should:

a. describe the general system of control in terms of the political, administrative and geographic configuration of the State;

b. provide for the possibility of the delegation of powers to a professional organisation such as a veterinary statutory body;

c. where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation;

d. prescribe the disciplinary powers that apply to the relevant professions.

Article 3.3.4.

Laboratories in the veterinary field

1. Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

a. reference laboratories, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;

b. laboratories designated by the State for carrying out the analysis of official samples;

c. laboratories recognised by the State as fit to conduct compulsory analyses by the private sector.

The veterinary legislation should define the conditions for the classification, approval, operations and supervision of laboratories at each level.

2. Laboratory reagents

Veterinary legislation should address the elements listed below:

a. procedures for authorising the reagents that are used to perform official analyses;

b. surveillance of marketing of reagents, where these can affect the quality of analyses required by the veterinary legislation;

c. quality assurance of reagents by manufacturers.

Annex V (contd)

Article 3.3.5.

Delegation of powers

1. General principles

The veterinary legislation should provide for the possibility of the competent authorities delegating specific tasks related to official activities.

The specific tasks delegated, the body(ies) to which the tasks are delegated and the conditions of supervision by the competent authority should be defined.

2. Animal health delegation

The veterinary legislation should provide for the possibility of the competent authority delegating specific tasks in the sector of animal health to individual professional veterinarians who are not civil servants.

For that purpose the veterinary legislation should:

a. define the field of activities and the specific tasks covered by the delegation;

b. provide for the control, supervision and financing of the delegation;

c. define the procedures for making delegations;

d. define the competencies to be held by persons receiving delegation;

e. define the conditions of withdrawals of delegations.

3. Delegation of functions relating to veterinary certification

Veterinary legislation should conform with Section 5 of the OIE Terrestrial Code concerning certification procedures, especially on the:

a. conditions of appointment or recognition of certifying officials;

b. role and responsibilities of the certifying officials;

c. conditions of certification;

d. means of supervision and financing of certification;

e. define the conditions of withdrawal of the delegation.

4. Delegation of functions relating to the identification of animals and traceability

a. Veterinary legislation should provide for the possibility of delegating operations, under the supervision of the competent authority, to the operators that are best placed to carry out and manage the identification systems.

b. Veterinary legislation should define the conditions of withdrawal of the delegation.

5. Relationships with stakeholders

To ensure transparency and facilitate implementation of the veterinary legislation, the competent authority should establish relationships with stakeholders, including by:

a. taking steps to ensure that stakeholders participate in the development of significant legislation and required follow up;

b. supporting, as appropriate, participation of stakeholders in international discussions.

Article 3.3.6.

Health provisions relating to animal production

1. Identification and traceability

Veterinary legislation should address the following elements:

a. the objectives and scope of animal identification;

b. the possibility to make animal identification compulsory for certain species, regions or function;

c. the power of the competent authority to control movements of animals and changes of ownership;

d. identification includes the marking of animals or groups of animals and the recording of corresponding data;

e. the use of identification data for veterinary matters;

f. the equipment and methods to be used and the qualifications of operators for the marking or tracing of animals as appropriate to each situation;

g. the type of data to be recorded and the responsibilities of each party, notably those of animal keepers;

h. for the conduct of checks and corrections, as may be required to ensure the reliability of information in the database, notably in respect of animals that have died or have been slaughtered for any reason;

i. respect for constitutional liberties by restricting the use, security and confidentiality of data.

2. Animal markets and other gatherings

Veterinary legislation should address the following elements:

a. registration of all permanent or temporary animal markets and other animal gatherings;

b. health measures to prevent disease transmission, including procedures for cleaning and disinfection, and animal welfare measures;

c. provision for compulsory veterinary checks at animal gatherings.

Annex V (contd)

3. Animal reproduction

Except where the animals or reproductive material are only used in a single holding, the veterinary legislation should address the elements listed below:

a. the health regulation of animal reproduction as appropriate;

b. health regulations may be implemented at the level of animals, genetic material, establishments or operators.

4. Animal feed

Veterinary legislation should address the elements listed below:

a. standards for the production and composition of animal feed;

b. registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations;

c. recall from the market of any product likely to present a hazard to human health or animal health.

5. Animal by-products (i.e. products not used for human consumption)

Veterinary legislation should address the elements listed below:

a. definition of the animal by-products subject of the legislation;

b. rules for collection, processing methods and authorised uses of animal by-products;

c. registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations;

d. definition of the rules to be applied by animal owners as appropriate.

6. Disinfection

Veterinary legislation should address the following elements:

a. the regulation of products and methods that are used for disinfection relating to animal diseases;

b. the use of disinfection at all critical points, notably during the transportation of animals.

Article 3.3.7.

Animal diseases

1. Surveillance

Veterinary legislation should address the following elements:

a. collection, transmission and utilisation of epidemiological data relevant to listed diseases;

b. an early warning system.

2. Disease prevention

Veterinary legislation should address the following elements:

a. specific rules for each listed disease;

b. support to stakeholders in proposing joint programmes;

c. the direct control by the competent authority of some disease prevention programmes;

d. compulsory programmes for some disease prevention when necessary.

3. Disease control

Veterinary legislation should address the following elements:

a. different lists of diseases, with provision (as appropriate) for:

i. emergency measures in accordance with established contingency plans;

ii. measures for prevention, control or eradication;

iii. surveillance measures;

b. the specification of mandatory control measures for certain diseases;

c. arrangements for the declaration of animal diseases including on the grounds of suspicion;

d. immediate technical measures including on the grounds of suspicion;

e. measures for official disease surveillance;

f. conditions for confirmation of diseases;

g. precautionary measures.

Veterinary legislation should provide for the following general measures:

a. definition of areas in which health measures are applied;

b. official publicising of measures;

c. listing of all measures requiring a legal basis;

d. measures to be implemented by the public force;

e. epidemiological investigations;

f. provisions for wild or protected animals;

g. conditions for restocking;

h. commercial restrictions.

Annex V (contd)

Contingency plan should be developed for certain diseases and, in addition to the general measures, should provide for:

a. administrative and logistic organisation;

b. exceptional powers of the competent authority;

c. special and temporary measures to address all identified risks to human or animal health.

Veterinary legislation should provide for the financing of animal disease control measures, notably:

a. operational expenses;

b. production losses;

c. owners compensation in the event of killing or slaughtering of animals, seizure or destruction of carcasses, meat, animal feed or other things.

Article 3.3.8.

Animal welfare measures

1. General provisions

Veterinary legislation should address the elements listed below:

a. general principles to ensure the protection of animals against cruelty, abuse, abandonment and avoidable suffering, in line with the OIE *Terrestrial Code*;

b. legal definition of cruelty as an offense, subject to penal action;

c. direct intervention of the competent authority in the case of neglect by animal keepers;

d. accepted practices for livestock, pets, animals used in scientific experiments, sport and leisure, and for wild animals, notably in relation to:

i. transport and handling;

ii. animal production and housing;

iii. slaughtering and killing;

iv. scientific experiments;

v. use in games, shows, exhibitions and zoos;

e. certain activities relating to animals may be restricted to the holders of appropriate qualifications or approvals.

2. Free-roaming and stray domestic animals

Veterinary legislation should address the elements listed below:

a. prohibition of abandonment of animals and of allowing animals to stray;

b. establishments where stray animals can be held and the conditions governing their operation;

c. the circumstances and the conditions of capture and of holding of stray animals;

d. the outcomes for these animals, including arrangements for veterinary interventions (including euthanasia in compliance with OIE standards), and for the transfer of ownership.

Article 3.3.9.

Veterinary products

1. Objectives

Veterinary legislation should address the following elements:

a. avoiding the presence of harmful residues in the food chain;

b. ensuring that the use of veterinary products does not give rise to human health risks.

2. General measures

Veterinary legislation should address the elements listed below:

a. definition of veterinary products, including any specific exclusions;

b. regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary products.

3. Raw materials and veterinary products

Veterinary legislation should address the elements listed below:

a. quality standards for raw materials used in the manufacture or composition of veterinary products and arrangements for checking quality;

b. establishment of the withdrawal periods and maximum residue limits for veterinary products as appropriate;

c. requirements for any substances that may interfere with the conduct of veterinary checks.

4. Authorisation of veterinary products

Veterinary legislation should ensure that only authorised veterinary products may be placed on the market.

Special provisions should be made for:

a. veterinary products that do not present any risk of residues or interference with the conduct of disease prevention and control programmes;

b. medicated feed;

c. products prepared by veterinarians or pharmacists;

d. emergencies and temporary situations.

Veterinary legislation should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.

In defining the procedures for seeking and granting authorisations, the legislation should:

a. describe the functioning of the competent authority concerned;

b. establish rules providing for the transparency of decisions.

Veterinary legislation may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

5. Quality of veterinary products

To give effect to the objectives identified above, veterinary legislation should address the elements listed below:

a. the conduct of clinical and non clinical trials to verify all claims made by the manufacturer, including analysis and dosage methods;

b. conditions for the conduct of trials;

c. qualifications of experts involved in trials;

d. surveillance for adverse effects arising from the use of veterinary products.

6. Establishments producing, storing and selling veterinary products

Veterinary legislation should address the following elements:

a. registration or authorisation of all operators importing, storing, processing, selling or otherwise distributing veterinary products or raw materials for use in making veterinary products;

b. definition of the responsibilities of operators;

c. good manufacturing practices as appropriate;

d. arrangements for informing the competent authority about traceability of products and adverse effects.

7. Commerce, distribution, use and traceability of veterinary products

Veterinary legislation should address the following elements:

a. control over the circulation and distribution of veterinary products and arrangement for traceability and condition of use;

b. establishment of rules of prescription and provision of veterinary products to the end user;

c. restricting to authorised professionals all commerce in veterinary products that are subject to prescription;

d. the supervision by an authorised professional of organisations approved for holding and use of veterinary products;

e. the regulation of advertising claims and other marketing and promotional activities.

Article 3.3.10.

Safeguards for the food production chain and traceability

1. Objectives

Veterinary legislation should address the following elements:

a. the control of the manufacturing process at all relevant levels in the food production chain;

b. requirements to assure food safety for the purpose of (i).

In addition, procedures may be implemented to allow food production appropriate to the economic situation.

2. General

Veterinary legislation should address the following elements in order to ensure the food safety of animal products:

a. recording all significant health events that occur during primary production;

b. prohibition of the marketing of infected products or products likely to be contaminated or hazardous for the consumer or for animal health;

c. inspection for food safety and food composition;

d. inspection of premises;

e. controls over the implementation of the legislation at all stages of the production, processing and distribution of food of animal origin;

f. establish that operators of food production premises have the primary responsibility for food safety;

g. obligations for producers to withdraw from the marketplace all products likely to be hazardous for human or animal health.

3. Products of animal origin intended for human or animal consumption

Veterinary legislation should address the following elements:

a. arrangements for inspection;

b. the conduct of inspection on the basis of veterinary expertise;

c. relevant health standards;

d. application of health identification marks, which are visible to the intermediary or final user.

Annex V (contd)

The competent authority should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

4. Premises and establishments pertaining to the food chain

Veterinary legislation should address the following elements as appropriate:

a. recording the coordinates of operators working within the food chain;

b. the implementation by operators of procedures based on HACCP principles;

c. prior authorisation of operators whose activities are likely to constitute a significant risk to human or animal health.

Article 3.3.11.

International movements and trade

1. Importation

Veterinary legislation should address the following elements:

a. the coordinates of importers and, as appropriate, their approval by the competent authority of the importing country;

b. the establishment by the competent authority of:

i. the list of goods to be subject to veterinary checks;

ii. the importation check points officially designated for each kind of goods;

iii. the kinds and procedures of checks to be performed;

iv. the standards with which animals and commodities proposed for importation must comply;

c. prevention of entry of listed goods and consignments into the country unless such goods have been subjected to the required veterinary checks;

d. objectivity and independence of inspectors.

2. Exports

Veterinary legislation should specify the conditions governing the provision of veterinary certification and any prohibitions, in conformity with relevant provisions of the OIE and of the Codex Alimentarius Commission.

It should also include provisions ensuring national involvement to relevant activities of the work of the OIE and the Codex Alimentarius and, if necessary, interministerial coordination allowing the harmonization of the positions taken by the country in these international organizations.

Annex VI

CHAPTER 4.2.

DESIGN AND IMPLEMENTATION OF IDENTIFICATION SYSTEMS TO ACHIEVE ANIMAL TRACEABILITY

EU comment

The EU thanks the OIE TAHSC and supports the proposed changes.

Article 4.2.1.

Introduction and objectives

These recommendations are based on the general principles presented in Article 4.1.1. The recommendations outline for Members the basic elements that need to be taken into account in the design and implementation of an *animal identification system* to achieve *animal traceability*. Whatever*animal identification system* the country adopts, it should comply with relevant OIE standards, including Chapters 5.10. to 5.12. for *animals* and animal products intended for export. Each country should design a programme in accordance with the scope and relevant performance criteria to ensure that the desired *animal traceability* outcomes can be achieved.

Article 4.2.2.

Definitions

For the purpose of this chapter:

Desired outcomes: describe the overall goals of a programme and are usually expressed in qualitative terms, e.g. 'to help ensure that *animals* and/or animal products are safe and suitable for use'. Safety and suitability for use could be defined in terms such as animal health, food safety, trade and aspects of animal husbandry.

Performance criteria: are specifications for performance of a programme and are usually expressed in quantitative terms, such as 'all *animals* can be traced to the *establishment* of birth within 48 hours of an enquiry'.

Reporting: means advising the *Veterinary Authority* and other partner organisations as appropriate in accordance with the procedures listed in the programme.

Scope: specifies the targeted species, population and/or production/trade sector within a defined area (country, *zone*) or *compartment* that is the subject of the *identification* and *traceability* programme.

Transhumance: periodic/seasonal movements of *animals* between different pastures within or between countries.

Article 4.2.3.

Key elements of the animal identification system

1. Desired outcomes

   Desired outcomes should be defined through consultation between the *Veterinary Authority* and other parties, which should include (depending on scope) animal producers and food processors, private sector veterinarians, scientific research organisations and other government agencies. Desired outcomes may be defined in terms of any or all of the following:

a) animal health (e.g. *disease surveillance* and notification; detection and control of *disease*; vaccination programmes);

b) public health (e.g. *surveillance* and control of zoonotic diseases and food safety);

c) management of emergencies e.g. natural catastrophies or man-made events;

d) trade (support for inspection and certification activities of *Veterinary Services*, as described in Chapters 5.10. to 5.12. which reproduce model international veterinary certificates);

e) aspects of animal husbandry such as animal performance, and genetic data.

2. Scope

Scope should also be defined through consultation between the *Veterinary Authority* and other parties, as discussed above. The scope of *animal identification systems* is often based on the definition of a species and sector, to take account of particular characteristics of the farming systems e.g. pigs in pork export production; poultry in a defined *compartment*; cattle within a defined FMD free *zone*. Different systems will be appropriate according to the production systems used in countries and the nature of their industries and trade.

3. Performance criteria

Performance criteria are also designed in consultation with other parties, as discussed above. The performance criteria depend on the desired outcomes and scope of the programme. They are usually described in quantitative terms according to the epidemiology of the *disease*. For example, some countries consider it necessary to trace susceptible *animals* within 24-48 hours when dealing with highly contagious *diseases* such as FMD and avian influenza. For food safety, animal tracing to support investigation of incidents may also be urgent. For chronic animal *diseases* that are not *zoonoses*, it may be considered appropriate that *animals* can be traced over a longer period.

4. Preliminary studies

In designing *animal identification systems* it is useful to conduct preliminary studies, which should take into account:

a) animal populations, species, distribution, *herd* management,

b) farming and industry structures, production and location,

c) animal health,

d) public health,

e) trade issues,

f) aspects of animal husbandry,

g) zoning and compartmentalisation,

h) animal movement patterns (including transhumance),

i) information management and communication,

j) availability of resources (human and financial),

k) social and cultural aspects,

l) stakeholder knowledge of the issues and expectations,

m) gaps between current enabling legislation and what is needed long term,

n) international experience,

o) national experience,

p) available technology options,

q) existing identification system(s),

r) expected benefits from the *animal identification systems* and *animal traceability* and to whom they accrue,

s) issues pertaining to data ownership and access rights,

t) reporting requirements.

Pilot projects may form part of the preliminary study to test the *animal identification system* and *animal traceability* and to gather information for the design and the implementation of the programme.

Economic analysis may consider costs, benefits, funding mechanisms and sustainability.

5. Design of the programme

a) General provisions

The programme should be designed in consultation with the stakeholders to facilitate the implementation of the *animal identification system* and *animal traceability*. It should take into account the scope, performance criteria and desired outcomes as well as the results of any preliminary study.

All the specified documentation should be standardised as to format, content and context.

To protect and enhance the integrity of the system, procedures should be incorporated into the design of the programme to prevent, detect and correct errors e.g. use of algorithms to prevent duplication of identification numbers and to ensure plausibility of data.

b) Means of animal identification

The choice of a physical animal or group identifier should consider elements such as the durability, human resources, species and age of the *animals* to be identified, required period of identification, cultural aspects, *animal welfare*, technology, compatibility and relevant standards, farming practices, production systems, animal population, climatic conditions, resistance to tampering, trade considerations, cost, and retention and readability of the identification method.

The *Veterinary Authority* is responsible for approving the materials and equipment chosen, to ensure that these means of animal identification comply with technical and field performance specifications, and for the supervision of their distribution. The *Veterinary Authority* is also responsible for ensuring that identifiers are unique and are used in accordance with the requirements of the *animal identification system*.

The *Veterinary Authority* should establish procedures for *animal identification* and *animal traceability* including:

i) the *establishment* of birth, and time period within which an *animal* is born;

ii) when *animals* are introduced into an *establishment*;

iii) when an *animal* loses its identification or the identifier becomes unusable;

iv) arrangements and rules for the destruction and/or reuse of identifiers;

v) penalties for the tampering and/or removal of official animal identification devices.

Where group identification without a physical identifier is adequate, documentation should be created specifying at least the number of *animals* in the group, the species, the date of identification, the person legally responsible for the *animals* and/or *establishment*. This documentation constitutes a unique group identifier and it should be updated to be traceable if there are any changes.

Where all *animals* in the group are physically identified with a group identifier, documentation should also specify the unique group identifier.

c) Registration

Procedures need to be incorporated into the design of the programme in order to ensure that relevant events and information are registered in a timely and accurate manner.

Depending on the scope, performance criteria and desired outcomes, records as described below should specify, at least, the species, the unique animal or group identifier, the date of the event, the identifier of the *establishment* where the event took place, and the code for the event itself.

i) Establishments/owners or responsible keepers

Establishments where *animals* are kept should be identified and registered, including at least their physical location (such as geographical coordinates or street address), the type of establishment and the species kept. The register should include the name of the person legally responsible for the *animals* at the establishment.

The types of establishments that may need to be registered include holdings (farms), assembly centres (e.g. agriculture shows and fairs, sporting events, transit centres, breeding centres), *markets*, *abattoirs*, rendering plants, dead stock collection points, transhumance areas, centres for necropsy and diagnosis, research centres, zoos, *border posts*, *quarantine stations*.

In cases where the registration of establishments is not applicable e.g. some transhumance systems, the animal owner, the owner's place of residence and the species kept should be recorded.

ii) Animals

Animal identification and species should be registered for each establishment/owner. Other relevant information about the *animals* at each establishment/owner may also be recorded (e.g. date of birth, production category, sex, breed, number of *animals* of each species, *animal identification* of the parents).

iii) Other events

The *registration* of animal movements is necessary to achieve *animal traceability*. When an *animal* is introduced into or leaves an establishment, these events constitute a movement.

Some countries classify birth, *slaughter* and *death* of the *animal* as movements. When establishments are not registered as part of the *animal identification system*, ownership and location changes constitute a movement record.

The information registered should include the date of the movement, the establishment from which the *animal* or group of *animals* was dispatched, the number of *animals* moved, the destination establishment, and any establishment used in transit. The ~~M~~movement ~~recording~~ may also include a description of the means of transport and the identification of the *vehicle*/*vessel* ~~identifier~~.

Procedures should be in place to maintain *animal traceability* during *transport* and when *animals* arrive at and leave an establishment.

The following events may also be registered:

- birth, *slaughter* and *death* of the *animal* (when not classified as a movement),
- attachment of the unique identifier to an *animal*,
- change of owner or keeper regardless of change of establishment,
- observation of an *animal* on an establishment (testing, health investigation, health certification, etc.),
- animal imported: a record of the *animal identification* from the *exporting country* should be kept and linked with the *animal identification* assigned in the *importing country*,
- animal exported: a record of the *animal identification* from the *exporting country* should be provided to the *Veterinary Authority* in the *importing country*,
- animal identifier lost or replaced,
- animal missing (lost, stolen, etc.),
- animal identifier retired (at *slaughter*, following loss of the identifier or *death* of the *animal* on a farm, at diagnostic *laboratories*, etc.).

d) Documentation

Documentation requirements should be clearly defined and standardised, according to the scope, performance criteria and desired outcomes and supported by the legal framework.

e) Reporting

Depending on the scope, performance criteria and desired outcomes, relevant information (such as *animal identification*, movement, events, changes in numbers of livestock, *establishments*) should be reported to the *Veterinary Authority* by the person responsible for the *animals*.

f) Information system

An information system should be designed according to the scope, performance criteria and desired outcomes. This may be paper based or electronic. The system should provide for the collection, compilation, storage and retrieval of information on matters relevant to *registration*. The following considerations are important:

- have the potential for linkage to traceability in the other parts of the food chain;
- minimize duplication;

Annex VI (contd)

- relevant components, including databases, should be compatible;
- confidentiality of data;
- appropriate safeguards to prevent the loss of data, including a system for backing up the data.

The *Veterinary Authority* should have access to this information system as appropriate to meet the scope, performance criteria and desired outcomes.

g) Laboratories

The results of diagnostic tests should record the animal identifier or the group identifier, the date of sample was taken from the *animal* and the establishment where the sample was collected.

h) Abattoirs, rendering plants, dead stock collection points, markets and assembly centres

Abattoirs, rendering plants, dead stock collection points, *markets* and assembly centres should document arrangements for the maintenance of *animal identification* and *animal traceability* in compliance with the legal framework.

These establishments are critical points for control of animal health and food safety.

Animal identification should be recorded on documents accompanying samples collected for analysis.

The components of the *animal identification system* operating within *abattoirs* should complement and be compatible with arrangements for tracking animal products throughout the food chain. At an *abattoir*, *animal identification* should be maintained during the processing of the *animal*'s carcass until the carcass is deemed fit for human consumption.

The *animal identification* and the establishment from which the *animal* was dispatched should be registered by the *abattoir*, rendering plant and dead stock collection points.

Abattoirs, rendering plants and dead stock collection points should ensure that identifiers are collected and disposed of according to the procedures established and regulated within the legal framework. These procedures should minimize the risk of unauthorized reuse and, if appropriate, should establish arrangements and rules for the reuse of identifiers.

Reporting of movement by *abattoirs*, rendering plants and dead stock collection points should occur according to the scope, performance criteria and desired outcomes and the legal framework.

i) Penalties

Different levels and types of penalties should be defined in the programme and supported by the legal framework.

6. Legal framework

The *Veterinary Authority*, with other relevant governmental agencies and in consultation with stakeholders, should establish a legal framework for the implementation and enforcement of *animal identification system* and *animal traceability* in the country. The structure of this framework will vary from country to country.

Animal identification, *animal traceability* and animal movement should be under the responsibility of the *Veterinary Authority*.

This legal framework should address:

i) desired outcomes and scope;

ii) obligations of the *Veterinary Authority* and other parties;

iii) organisational arrangements, including the choice of technologies and methods used for the *animal identification system* and *animal traceability*;

iv) management of animal movement;

v) confidentiality of data;

vi) data access / accessibility;

vii) checking, verification, inspection and penalties;

viii) where relevant, funding mechanisms;

ix) where relevant, arrangements to support a pilot project.

7. Implementation

a) Action plan

For implementing the *animal identification system*, an action plan should be prepared specifying the timetable and including the milestones and performance indicators, the human and financial resources, and checking, enforcement and verification arrangements.

The following activities should be addressed in the action plan:

i) Communication

The scope, performance criteria, desired outcomes, responsibilities, movement and registration requirements and sanctions need to be communicated to all parties.

Communication strategies need to be targeted to the audience, taking into account elements such as the level of literacy (including technology literacy) and spoken languages.

ii) Training programmes

It is desirable to implement training programmes to assist the *Veterinary Services* and other parties.

iii) Technical support

Technical support should be provided to address practical problems.

b) Checking and verification

Checking activities should start at the beginning of the implementation to detect, prevent and correct errors and to provide feedback on programme design.

Verification should begin after a preliminary period as determined by the *Veterinary Authority* in order to determine compliance with the legal framework and operational requirements.

Annex VI (contd)

c) Auditing

Auditing should be carried out under the authority of the *Veterinary Authority* to detect any problems with the *animal identification system* and *animal traceability* and to identify possible improvements.

d) Review

The programme should be subject to periodic review, taking into account the results of checking, verification and auditing activities.

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Annex VII

CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

EU comment

The EU can support the proposed changes.

Article 4.3.1.

Introduction

For the purposes of the *Terrestrial Code*, 'zoning' and 'regionalisation' have the same meaning.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, given the difficulty of establishing and maintaining a *disease* free status for an entire territory, especially for *diseases* the entry of which is difficult to control through measures at national boundaries, there may be benefits to a Member in establishing and maintaining a *subpopulation* with a distinct health status within its territory. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

Zoning and compartmentalisation are procedures implemented by a Member under the provisions of this chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of *disease* control and/or *international trade*. While zoning applies to an animal *subpopulation* defined primarily on a geographical basis (using natural, artificial or legal boundaries), compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to biosecurity. In practice, spatial considerations and good management including *biosecurity plans* play important roles in the application of both concepts.

A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of limited *outbreaks* of a specified *disease* within an otherwise free country or *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

This chapter is to assist OIE Members wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of *disease*.

Before trade in *animals* or their products may occur, an *importing country* needs to be satisfied that its *animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its territory.

As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within a Member's territory. Zoning may encourage the more efficient use of resources within certain parts of a country and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following a *disease outbreak*, the use of compartmentalisation may allow a Member to take advantage of epidemiological links among *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the continuation of trade.

Zoning and compartmentalisation cannot be applied to all *diseases* but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.

Annex VII (contd)

To regain free status following a *disease outbreak* in a *zone* or *compartment*, Members should follow the recommendations in the relevant *disease* chapter in the *Terrestrial Code*.

Article 4.3.2.

General considerations

The *Veterinary Services* of an *exporting country* which is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters in the *Terrestrial Code*, including those on *surveillance*, and the *identification* and *traceability* of live *animals*. The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming a distinct *animal health status* for the given *zone* or *compartment* under consideration.

The procedures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* ~~should be appropriate to the particular circumstances, and~~ will depend on the epidemiology of the *disease*, in particular, the presence and ~~importance~~ role of susceptible wildlife ~~species,~~ and environmental factors, and ~~appropriate~~ on the application of biosecurity measures.

The authority, organisation and infrastructure of the *Veterinary Services*, including *laboratories*, should be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *zone* or *compartment*. The final authority of the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*.

In the context of maintaining the health status of a *population*, references to 'import', 'importation' and 'imported animals/products' found in the *Terrestrial Code* apply both to importation into a country and to the movement of *animals* and their products into *zones* and *compartments*. Such movements should be the subject of appropriate measures to preserve the *animal health status* of the *zone/compartment*.

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry and production system, in the case of a *compartment*) including *disease surveillance* and diagnosis.

Biosecurity and *surveillance* are essential components of zoning and compartmentalisation, and the arrangements should be developed through cooperation of industry and *Veterinary Services*.

Industry's responsibilities include the application of biosecurity measures, documenting and recording movements of *animals* and personnel, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.

The *Veterinary Services* should provide movement certification, and carry out documented periodic inspections of facilities, biosecurity measures, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting and *laboratory* diagnostic examinations.

Article 4.3.3.

Principles for defining and establishing a zone or compartment, including protection and containment zones

In conjunction with the above considerations, the following principles should apply when Members define a *zone* or a *compartment*.

1. The extent of a *zone* and its geographical limits should be established by the *Veterinary Authority* on the basis of natural, artificial and/or legal boundaries, and made public through official channels.

2. A *protection zone* may be established to preserve the health status of *animals* in a free country or *zone*, from adjacent countries or *zones* of different *animal health status*. Measures should be implemented based on the epidemiology of the *disease* under consideration to prevent introduction of the pathogenic agent and to ensure early detection.

   These measures should include intensified movement control and *surveillance* and may include:

   a) *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations;

   b) vaccination of all or at risk susceptible *animals*;

   c) testing and/or vaccination of *animals* moved;

   d) specific procedures for sample handling, sending and testing;

   e) enhanced biosecurity including cleansing – *disinfection* procedures for transport means, and possible compulsory routes;

   f) specific *surveillance* of susceptible wildlife species and relevant *vectors*;

   g) awareness campaigns to the public or targeted at breeders, traders, hunters, *veterinarians*.

   The application of these measures can be in the entire free *zone* or in a defined area within and/or outside the free *zone*.

3. In the event of limited *outbreaks* in a country or *zone* previously free of a *disease*, a *containment zone* may be established for the purposes of trade. Establishment of a *containment zone* should be based on a rapid response including:

   a) appropriate standstill of movement of *animals* and other *commodities* upon notification of suspicion of the specified *disease* and the demonstration that the *outbreaks* are contained within this zone through epidemiological investigation (trace-back, trace-forward) after confirmation of *infection*. The primary *outbreak* has been identified and investigations on the likely source of the *outbreak* have been carried out ~~should be identified~~ and all *cases* shown to be epidemiologically linked.

   b) A *stamping-out policy* or another effective control strategy aimed at eradicating the *disease* should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*.

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c) Measures consistent with the disease specific chapter should be in place to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing *surveillance* in the *containment zone*.

d) For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.

e) The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated, once the *containment zone* is clearly established, irrespective of the provisions of the disease specific chapter.

f) The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for *international trade* can be shown to have originated outside the *containment zone*.

g) The recovery of the free status of the *containment zone* should follow the provisions of the disease specific chapter.

4. The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.

5. *Animals* and *herds* belonging to such *subpopulations* need to be recognisable as such through a clear epidemiological separation from other animals and all things presenting a *disease risk*. For a *zone* or *compartment*, the *Veterinary Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the establishment and maintenance of its health status through a *biosecurity plan*. The measures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors, the health status of *animals* in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of *animals*, and commercial management and husbandry practices), and *surveillance*.

6. Relevant *animals* within the *zone* or *compartment* should be identified in such a way that their ~~history can be audited~~ movements are traceable. Depending on the system of production, identification may be done at the *herd*, *flock* lot or individual animal level. Relevant animal movements into and out of the *zone* or *compartment* should be well documented~~,~~ and controlled ~~and supervised~~. The existence of a valid *animal identification system* is a prerequisite to assess the integrity of the *zone* or *compartment*.

7. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the routine operating procedures to provide clear evidence that the *surveillance* conducted, the live *animal identification* and *traceability* system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on animal movement controls, the plan should include *herd* or *flock* production records, feed sources, *surveillance* results, birth and *death* records, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk* mitigation. The information required may vary according to the species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly re-assessed and the measures adjusted accordingly.

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Annex VII (contd)

CHAPTER 4.4.

APPLICATION OF COMPARTMENTALISATION

EU comment

The EU can support the proposed change.

Article 4.4.1.

Introduction and objectives

The recommendations in this chapter provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 4.3. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for *disease* management.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, establishing and maintaining a *disease*-free status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based o~~f~~n management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

Compartmentalisation is not a new concept for *Veterinary Services*; in fact, it has been applied for a long time in many *disease* control programmes that are based on the concept of *disease*-free *herds/flocks*.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of *subpopulations*.

For example, an animal production operation in an infected country or *zone* might have biosecurity measures and management practices that result in negligible *risk* from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease*-specific separation between *subpopulations*.

In *disease*-free countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* should be under the responsibility of the *Veterinary Authority* in the country. For the purposes of this chapter, compliance by the Members with Chapters 1.1. and 3.1. is an essential prerequisite.

Article 4.4.2.

Principles for defining a compartment

A *compartment* may be established with respect of a specific *disease* or *diseases*. A *compartment* should be clearly defined, indicating the location of all its components including *establishments*, as well as related functional units (such as feed mills, *slaughterhouses*, rendering plants, etc.), their interrelationships and their contribution to an epidemiological separation between the *animals* in a *compartment* and *subpopulations* with a different health status. The definition of *compartment* may revolve around *disease* specific epidemiological factors, animal production systems, biosecurity practices infrastructural factors and *surveillance*.

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Article 4.4.3.

Separation of a compartment from potential sources of infection

The management of a *compartment* should provide to the *Veterinary Authority* documented evidence on the following:

1. Physical or spatial factors that affect the status of biosecurity in a compartment

   While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and *surveillance* measures:

   a) disease status in adjacent areas and in areas epidemiologically linked to the *compartment*;

   b) location, disease status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:

      i) *flocks* or *herds* with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;

      ii) *slaughterhouses*, rendering plants or feed mills;

      iii) *markets*, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

2. Infrastructural factors

   Structural aspects of the *establishments* within a *compartment* contribute to the effectiveness of its biosecurity. Consideration should be given to:

   a) fencing or other effective means of physical separation;

   b) facilities for people entry including access control, changing area and showers;

   c) *vehicle* access including washing and *disinfection* procedures;

   d) *unloading* and *loading* facilities;

   e) isolation facilities for introduced *animals*;

   f) facilities for the introduction of material and equipment;

   g) infrastructure to store feed and veterinary products;

   h) disposal of carcasses, manure and waste;

   i) water supply;

   j) measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;

k) air supply;

l) feed supply/source.

More detailed recommendations for certain *establishments* can be found in Sections 4 and 6 of the *Terrestrial Code*.

3. Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

a) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;

b) the critical control points for each pathway;

c) measures to mitigate exposure for each critical control point;

d) standard operating procedures including:

   i) implementation, maintenance, monitoring of the measures,

   ii) application of corrective actions,

   iii) verification of the process,

   iv) record keeping;

e) contingency plan in the event of a change in the level of exposure;

f) reporting procedures to the *Veterinary Authority*;

g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;

h) the *surveillance* programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the *biosecurity plan* in accordance with the level of *risk* for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the disease agent into the *compartment*.

4. Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid *traceability* system. All *animals* within a *compartment* should be individually identified and registered in such a way that their history and movements can be documented and audited. In cases where individual identification may not be feasible, such as broilers and day-old chicks, the *Veterinary Authority* should provide sufficient assurance of *traceability*.

Annex VII (contd)

All animal movements into and out of the *compartment* should be recorded at the *compartment* level, and when needed, based on a *risk assessment*, certified by the *Veterinary Authority*. Movements within the *compartment* need not be certified but should be recorded at the *compartment* level.

Article 4.4.4.

Documentation

Documentation should provide clear evidence that the biosecurity, *surveillance*, *traceability* and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include *herd* or *flock* production records, feed sources, *laboratory* tests, birth and *death* records, the visitor logbook, morbidity history, medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Terrestrial Code* chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary Authority* a baseline animal health report indicating the presence or absence of OIE *listed diseases*. This report should be regularly updated to reflect the current animal health situation of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration should be available to enable interpretation of *surveillance* data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information should be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary Authority*.

Article 4.4.5.

Surveillance for the agent or disease

The *surveillance* system should comply with Chapter 1.4. on surveillance and the specific recommendations for *surveillance* for the *disease(s)* for which the *compartment* was defined, if available.

If there is an increased *risk* of exposure to the agent for which the *compartment* has been defined, the sensitivity of the internal and external *surveillance* system should be reviewed and, where necessary, increased. At the same time, biosecurity measures in place should be reassessed and increased if necessary.

1. Internal surveillance

Surveillance should involve the collection and analysis of *disease/infection* data so that the *Veterinary Authority* can certify that the animal *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A *surveillance* system that is able to ensure early detection in the event that the agent enters a *subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different *surveillance* strategies may be applied to achieve the desired confidence in *disease* freedom.

2. External surveillance

The biosecurity measures applied in a *compartment* should be appropriate to the level of exposure of the *compartment*. External *surveillance* will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of active and passive *surveillance* is necessary to achieve the goals described above. Based on the recommendations of Chapter 1.4., targeted *surveillance* based on an assessment of *risk* factors may be the most efficient *surveillance* approach. Targeted *surveillance* should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 4.4.6.

Diagnostic capabilities and procedures

Officially-designated *laboratory* facilities complying with the OIE standards for quality assurance, as defined in Chapter 1.1.3. of the *Terrestrial Manual*, should be available for sample testing. All *laboratory* tests and procedures should comply with the recommendations of the *laboratory* for the specific *disease*. Each *laboratory* that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.4.7.

Emergency response and notification

Early detection, diagnosis and notification of *disease* are critical to minimize the consequences of *outbreaks*.

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, the free status of the *compartment* should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Chapter 1.1.

In case of an occurrence of any infectious *disease* not present according to the baseline animal health report of the *compartment* referred to in Article 4.4.4., the management of the *compartment* should notify the *Veterinary Authority*, and initiate a review to determine whether there has been a breach in the biosecurity measures. If a significant breach in biosecurity, even in the absence of *outbreak*, is detected, export certification as a free *compartment* should be suspended. Disease free status of the *compartment* may only be reinstated after the *compartment* has adopted the necessary measures to re-establish the original biosecurity level and the *Veterinary Authority* re-approves the status of the *compartment*.

In the event of a *compartment* being at risk from a change, in the surrounding area, in the disease situation for which the *compartment* was defined, the *Veterinary Authority* should re-evaluate without delay the status of the *compartment* and consider whether any additional biosecurity measures are needed to ensure that the integrity of the *compartment* is maintained.

Article 4.4.8.

Supervision and control of a compartment

The authority, organisation, and infrastructure of the *Veterinary Services*, including *laboratories*, should be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *compartment*.

Annex VII (contd)

The *Veterinary Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this chapter and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.

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Annex VIII

CHAPTER 4.6.

COLLECTION AND PROCESSING OF BOVINE, SMALL RUMINANT AND PORCINE SEMEN

EU comment

The EU can support the proposed changes.

Article 4.6.1.

General considerations

The purposes of official sanitary control of semen production are to:

1. maintain the health of *animals* on an *artificial insemination centre* at a level which permits the international distribution of semen with a negligible risk of infecting other *animals* or humans with pathogens transmissible by semen;

2. ensure that semen is hygienically collected, processed and stored.

Artificial insemination centres should comply with recommendations in Chapter 4.5.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 4.6.2.

Conditions applicable to testing of bulls and teaser animals

Bulls and teaser animals should enter an *artificial insemination centre* only when they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

   The *animals* should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

   a) Bovine brucellosis – Point 3 or 4 of Article 11.3.5.

   b) Bovine tuberculosis – Point 3 or 4 of Article 11.6.5.

   c) Bovine viral diarrhoea-mucosal disease (BVD-MD)

      The *animals* should be subjected to:

      i) a virus isolation test or a test for virus antigen, with negative results; and

      ii) a serological test to determine the serological status of every *animal*.

   d) Infectious bovine rhinotracheitis-infectious pustular vulvovaginitis

      If the *artificial insemination centre* is to be considered as infectious bovine rhinotracheitis-infectious pustular vulvovaginitis free (IBR/IPV), the *animals* should either:

i) come from an IBR/IPV free *herd* as defined in Article 11.11.3.; or

ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.

e) Bluetongue

The *animals* should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* of origin of the *animals*.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, bulls and teaser animals should be kept in a pre-entry isolation facility for at least 28 days. The *animals* should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, except for *Campylobacter fetus* subsp. *venerealis* and *Tritrichomonas foetus*, for which testing may commence after 7 days in pre-entry isolation. All the results should be negative except in the case of BVD-MD antibody serological testing (see point 2b)i) below).

a) Bovine brucellosis

The *animals* should be subjected to a serological test with negative results.

b) BVD-MD

i) All *animals* should be tested for viraemia as described in point 1c) above.

Only when all the *animals* in pre-entry isolation test negative for viraemia, may the *animals* enter the semen collection facilities upon completion of the 28-day pre-entry isolation period.

ii) After 21 days in pre-entry isolation, all *animals* should be subjected to a serological test to determine the presence or absence of BVD-MD antibodies.

iii) Only if no sero-conversion occurs in the *animals* which tested seronegative before entry into the pre-entry isolation facility, may any *animal* (seronegative or seropositive) be allowed entry into the semen collection facilities.

iv) If sero-conversion occurs, all the *animals* that remain seronegative should be kept in pre-entry isolation until there is no more seroconversion in the group for a period of 3 weeks. Serologically positive *animals* may be allowed entry into the semen collection facilities.

c) *campylobacter fetus* subsp. *venerealis*

i) *Animals* less than 6 months old or kept since that age only in a single sex group prior to pre-entry isolation should be tested once on a preputial specimen, with a negative result.

ii) *Animals* aged 6 months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

d) *Tritrichomonas foetus*

i) *Animals* less than 6 months old or kept since that age only in a single sex group prior to pre-entry isolation, should be tested once on a preputial specimen, with a negative result.

ii) *Animals* aged 6 months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

e) IBR-IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any *animal* tests positive, the *animal* should be removed immediately from the pre-entry isolation facility and the other *animals* of the same group should remain in pre-entry isolation and be retested, with negative results, not less than 21 days after removal of the positive *animal*.

f) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

3. Testing programme for bulls and teasers resident in the semen collection facilities

All bulls and teasers resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

a) Bovine brucellosis

b) Bovine tuberculosis

c) BVD-MD

Animals negative to previous serological tests should be retested to confirm absence of antibodies.

Should an *animal* become serologically positive, every ejaculate of that *animal* collected since the last negative test should be either discarded or tested for virus with negative results.

d) *campylobacter fetus* subsp. *venerealis*

i) A preputial specimen should be tested.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

e) Bluetongue

The *animals* should comply with the provisions referred to in Article 8.3.11.

f) *Tritrichomonas foetus*

i) A preputial specimen should be cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

g) IBR-IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should comply with the provisions in point 2)c) of Article 11.11.3.

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4. Testing for BVD-MD prior to the initial dispatch of semen from each serologically positive bull

Prior to the initial dispatch of semen from BVD-MD serologically positive bulls, a semen sample from each *animal* should be subjected to a virus isolation or virus antigen test for BVD-MD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.

5. Testing of frozen semen for IBR/IPV in artificial insemination centres not considered as IBR/IPV free

Each aliquot of frozen semen should be tested as per Article 11.11.7.

Article 4.6.3.

Conditions applicable to testing of rams/bucks and teaser animals

Rams/bucks and teaser animals should only enter an *artificial insemination centre* if they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

The *animals* should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

a) Caprine and ovine brucellosis – Article 14.1.6.

b) Ovine epididymitis – Article 14.7.3.

c) Contagious agalactia – Points 1 and 2 of Article 14.3.1.

d) Peste des petits ruminants – Points 1, 2, and 4 or 5 of Article 14.8.7.

e) Contagious caprine pleuropneumonia – Article 14.4.7., depending on the CCPP status of the country or *zone* of origin of the *animals*.

f) Paratuberculosis – Free from clinical signs for the past 2 years.

g) Scrapie – Comply with Article 14.9.8. if the *animals* do not originate from a scrapie free country or *zone* as defined in Article 14.9.3.

h) Maedi-visna – Article 14.6.2.

i) Caprine arthritis/encephalitis – Article 14.2.2. in the case of goats.

j) Bluetongue

The *animals* should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* of origin of the *animals*.

k) Tuberculosis — In the case of goats, a single or comparative tuberculin test, with negative results.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, rams/bucks and teasers should be kept in a pre-entry isolation facility for at least 28 days. The *animals* should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.

a) Caprine and ovine brucellosis – Point 1c) of Article 14.1.8.

b) Ovine epididymitis – Points 1d) and 2 of Article 14.7.4.

c) Maedi-visna and caprine arthritis/encephalitis – Test on *animals* and semen.

d) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

3. Testing programme for rams/bucks and teasers resident in the semen collection facilities

All rams/bucks and teasers resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

a) caprine and ovine brucellosis;

b) ovine epididymitis;

c) Maedi-visna and caprine arthritis/encephalitis;

d) tuberculosis (for goats only);

e) bluetongue.

The *animals* should comply with the provisions referred to in Article 8.3.11.

Article 4.6.4.

Conditions applicable to testing of boars

Boars should only enter an *artificial insemination centre* if they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

The *animals* should be clinically healthy, physiologically normal and comply with the following requirements within 30 days prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

a) Porcine brucellosis – Article 15.3.3.

b) Foot and mouth disease – Articles 8.5.12., 8.5.13. or 8.5.14.

c) Aujeszky's disease – Article 8.2.8. or Article 8.2.9.

~~d. Teschovirus encephalomyelitis – Article 15.5.4. or Article 15.5.6.~~

~~c~~d) Transmissible gastroenteritis – Article 15.6.2.

~~f~~e) Swine vesicular disease – Article 15.4.5. or Article 15.4.7.

~~g~~f) African swine fever – Article 15.1.5. or Article 15.1.6.

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~~H~~g) Classical swine fever – Article 15.2.5. or Article 15.2.6.

~~I~~h) Porcine reproductive and respiratory syndrome – Test complying with the standards in the *Terrestrial Manual*.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, boars should be kept in a pre-entry isolation facility for at least 28 days. The *animals* should be subjected to diagnostic tests as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.

a) Porcine brucellosis – Article 15.3.5.

b) Foot and mouth disease – Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18.

c) Aujeszky's disease – Articles 8.2.12., 8.2.13. or 8.2.14.

~~d. Teschovirus encephalomyelitis – Article 15.5.8. or Article 15.5.9.~~

~~e~~d) Transmissible gastroenteritis – Article 15.6.4.

~~f~~e) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.

~~g~~f) African swine fever – Article 15.1.8. or Article 15.1.9.

~~h~~g) Classical swine fever – Article 15.2.8. or Article 15.2.9.

~~i~~h) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

3. Testing programme for boars resident in the semen collection facilities

All boars resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

a) Porcine brucellosis – Article 15.3.5.

b) Foot and mouth disease – Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18.

c) Aujeszky's disease – Articles 8.2.12., 8.2.13. or 8.2.14.

~~d. Teschovirus encephalomyelitis – Article 15.5.8. or Article 15.5.9.~~

~~e~~d) Transmissible gastroenteritis – Article 15.6.4.

~~f~~e) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.

~~g~~f) African swine fever – Article 15.1.8. or Article 15.1.9.

~~h~~g) Classical swine fever – Article 15.2.8. or Article 15.2.9.

~~i~~h) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

Article 4.6.5.

General considerations for hygienic collection and handling of semen

Observation of the recommendations described in the Articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.

Article 4.6.6.

Conditions applicable to the collection of semen

1. The floor of the mounting area should be clean and provide safe footing. A dusty floor should be avoided.

2. The hindquarters of the teaser, whether a dummy or a live teaser animal, should be kept clean. A dummy should be cleaned completely after each period of collection. A teaser animal should have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animals should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.

3. The hand of the person collecting the semen should not come into contact with the *animal*'s penis. Disposable gloves should be worn by the collector and changed for each collection.

4. The artificial vagina should be cleaned completely after each collection where relevant. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.

5. The lubricant used should be clean. The rod used to spread the lubricant should be clean and should not be exposed to dust between successive collections.

6. The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.

7. When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the *animal* has inserted its penis without ejaculating.

8. The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.

9. After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

Article 4.6.7.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory

1. Diluents

   a) All receptacles used should have been sterilised.

   b) Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.

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c) If the constituents of a diluent are supplied in commercially available powder form, the water used should have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.

d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free of pathogens or sterilised; milk heat-treated at 92°C for 3-5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives should also be sterilized before use.

e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.

f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: gentamicin (250 μg), tylosin (50 μg), lincomycin-spectinomycin (150/300 μg); penicillin (500 IU), streptomycin (500 μg), lincomycin-spectinomycin (150/300 μg); or amikacin (75μg), divekacin (25μg).

The names of the antibiotics added and their concentration should be stated in the *international veterinary certificate*.

2. Procedure for dilution and packing

a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.

b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.

c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved *disinfection* techniques.

d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage of semen

Semen for export should be stored separately from other genetic material not meeting the requirements of this chapter with fresh liquid nitrogen in sterilised/sanitised flasks before being exported.

Semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal Recording (ICAR)[1].

Prior to export, semen straws or pellets should clearly and permanently be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of an *Official Veterinarian*. The contents of the container or flask should be verified by the *Official Veterinarian* prior to sealing with an official numbered seal before export and accompanied by an *international veterinary certificate* listing the contents and the number of the official seal.

4. Sperm sorting

Equipment used for sex-sorting sperm should be clean and disinfected between *animals* according to the recommendations of the licencer of the system.

Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from *animals* of same or better health status.

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1. The ICAR international standards on straws are contained in Recording Guidelines - Appendices to the international agreement of recording practices. The text of this document is available at the following web site: www.icar.org

Annex IX

CHAPTER 5.2.

CERTIFICATION PROCEDURES

EU comment

The EU thanks the OIE TAHSC and supports the proposed change.

Article 5.2.1.

Protection of the professional integrity of the certifying veterinarian

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the certifying *veterinarian* should be respected and safeguarded according to Chapters 3.1. and 3.2.

It is essential to include in any requirements only those specific statements that can be accurately and honestly signed by a certifying *veterinarian*. For example, these requirements should not include certification of an area as being free from *diseases* other than ~~that are not~~ *notifiable diseases*, or the occurrence of which the signing *veterinarian* is not necessarily informed about. It is unacceptable to ask for certification for events which will take place after the document is signed when these events are not under the direct control and supervision of the signing *veterinarian*.

Certification of freedom from *diseases* based on purely clinical freedom and *herd* history is of limited value. This is also true of *diseases* for which there is no specific diagnostic test, or the value of the test as a diagnostic aid is limited.

The note of guidance referred to in Article 5.1.1. is not only to inform the signing *veterinarian* but also to safeguard professional integrity.

Article 5.2.2.

Certifying veterinarians

Certifying *veterinarian* should:

1. be authorised by the *Veterinary Authority* of the *exporting country* to sign *international veterinary certificates*;

2. only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party ;

3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying *veterinarian* should have verified or be in possession of that documentation before signing;

4. have no conflict of interest in the commercial aspects of the *animals* or animal products being certified and be independent from the commercial parties.

Article 5.2.3.

Preparation of international veterinary certificates

Certificates should be drawn up in accordance with the following principles:

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1. Certificates should be designed so as to minimize the potential for fraud including use of a unique identification number, or other appropriate means to ensure security. Paper certificates should bear the signature of the certifying *veterinarian* and the official identifier (stamp) of the issuing *Veterinary Authority*. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.

2. Certificates should be written using terms that are simple, unambiguous and as easy to understand as possible, without losing their legal meaning.

3. If so required, certificates should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the certifying *veterinarian*.

4. Certificates should require appropriate identification of *animals* and animal products except where this is impractical (e.g. *day-old birds*).

5. Certificates should not require a *veterinarian* to certify matters that are outside his/her knowledge or which he/she cannot ascertain and verify.

6. Where appropriate, when presented to the certifying *veterinarian*, certificates should be accompanied by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.

7. The text of a certificate should not be amended except by deletions which should be signed and stamped by the certifying *veterinarian*.

8. The signature and stamp should be in a colour different from that of the printing of the certificate. The stamp may be embossed instead of being a different colour.

9. Replacement certificates may be issued by a *Veterinary Authority* to replace certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These replacements should be provided by the issuing authority and be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and where possible, returned to the issuing authority.

10. Only original certificates are acceptable.

Article 5.2.4.

Electronic certification

1. Certification may be provided by electronic documentation sent directly from the *Veterinary Authority* of the *exporting country* to the *Veterinary Authority* of the *importing country*. Such systems also normally provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The certifying *veterinarian* should have access to all information such as *laboratory* results and *animal identification* data.

2. Electronic certificates may be in a different format but should carry the same information as conventional paper certificates.

3. The *Veterinary Authority* should have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.

4. The certifying *veterinarian* should be officially responsible for the secure use of his/her electronic signature.

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Annex X

CHAPTER 6.3.

THE CONTROL OF HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE IN ANIMAL FEED

EU comment

The EU thanks the OIE TAHSC and supports the proposed changes, but has some comments.

Article 6.3.1.

Introduction

Animal feed is a critical component of the food chain that has a direct impact on animal health and welfare and also on food safety and public health.

Historically, the OIE primarily addressed animal feed as an important pathway for the entry and spread of contagious epidemic *diseases*, such as foot and mouth disease, swine vesicular disease and avian influenza. In recent years, the role of feed as a *vector* for disease agents, including zoonotic organisms, was a focus of standards development in regards to bovine spongiform encephalopathy. Animal feed and feed ingredients are widely traded internationally and trade disruptions have the potential to impact economies in both developed and developing countries. Since 2002 the OIE has expanded its zoonotic *disease* mandate to encompass animal production food safety, working in collaboration with the Codex Alimentarius Commission (CAC) and other international organisations. In 2006 the International Committee resolved that the OIE should develop guidance on foodborne *zoonoses* and animal feeding, complementing relevant CAC texts.

Article 6.3.2.

Objective and scope

The objective of this chapter is to provide guidance on animal feeding in relation to animal health and to complement the guidance provided by the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) which deals primarily with food safety, and related other Codex texts covering animal feeding, e.g. Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001).

This chapter aims at ensuring the control of animal and public health hazards through adherence to recommended practices during the production (growing, procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced animal feed and feed ingredients for terrestrial *animals*.

This chapter applies to the production and use of all products destined for animal feed and feed ingredients at all levels whether produced commercially or on farm. It also includes grazing or free-range feeding, forage crop production and water for drinking. Swill feeding is a particular aspect of on-farm practice that is specifically addressed because of its recognised role in *disease* transmission.

This chapter deals with feed for terrestrial *animals* (except bees).

Article 6.3.3.

Definitions

Contamination: means the unwanted presence of a material, infectious agent or product in a feed or feed ingredient that is potentially harmful to animal or public health or restricted under current regulations.

Feed: means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial *animals* (except bees).

Feed additive: means any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value or other effect on the *animal*, which affects the characteristics of feed or of the animal products. Microorganisms, enzymes, pH regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration. This excludes veterinary drugs.

Feed ingredient: means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the *animal*'s diet, including feed additives. Ingredients are of plant (including aquatic plants) or terrestrial or aquatic animal origin, or other organic or inorganic substances.

Article 6.3.4.

General principles

1. Roles and responsibilities

The *Competent Authority* has the legal power to set and enforce regulatory animal feeding requirements, and has final responsibility for verifying that these requirements are met. The *Competent Authority* may establish regulatory requirements for relevant parties to provide it with information and assistance. Refer to Chapters 3.1. and 3.2. of the *Terrestrial Code.*

Those involved in the production and use of animal feed and feed ingredients have the responsibility to ensure that these products meet regulatory requirements. Appropriate contingency plans should be in place to enable tracing and recall of non-compliant products. All personnel involved in the manufacture, storage and handling of feed and feed ingredients should be adequately trained and aware of their role and responsibility in preventing the introduction or spread of hazards. Manufacturing equipment, storage and transport facilities should be adequate and maintained in good working order and in a sanitary condition.

EU comment

In the first sentence of the paragraph above, the word "primary" should be added before "responsibility", since responsibility is shared at different levels.

Moreover it should be highlighted that the second sentence does not imply that end users (including the ones who mix on farm) should have a complete "contingency plan" but only keep data as part of a wider plan. Thus, the words "or records where applicable" should be added after the words "contingency plans".

Those providing specialist services to producers and to the feed industry (e.g. private *veterinarians*, nutritionists and laboratories) may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. disease reporting, quality standards, transparency).

2. Regulatory safety standards

All feed and feed ingredients should meet regulatory safety standards. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be taken into account in defining limits and tolerances for hazards.

3. Risk analysis (risk assessment, risk management and risk communication)

Internationally accepted principles and practices on *risk analysis* (Section 2 of the *Terrestrial Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while recognising the different *risk assessment* methodologies used in animal and public health.

4. Good practices

Where national guidelines exist, good agricultural practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them or adopt suitable international standards or recommendations.

Where appropriate, Hazard Analysis and Critical Control Point (HACCP) principles should be followed to control hazards that may occur in the manufacture, distribution and feeding of feed and feed additives and feed ingredients.

5. Geographic and environmental considerations

Epidemiological links between potential sources of hazards for animal health or food safety should be considered when assessing water sources, land or facilities for suitability for the production of animal feed and feed ingredients. Animal health considerations include factors such as disease status, location of quarantined premises and existence of *zones/compartments* of specified health status. Food safety considerations include factors such as industrial operations that generate pollutants and waste treatment plants.

6. Zoning and compartmentalisation

Feed is an important component of biosecurity and needs to be considered when defining a *compartment* or *zone* in accordance with Chapter 4.3. of the *Terrestrial Code*.

7. Sampling and analysis

Sampling and analysis should be based on scientifically recognised principles and procedures.

8. Labelling

Labelling should be informative, unambiguous, legible and conspicuously placed on the package if sold in package form and on the waybill and other sales documents if sold in bulk, un-packaged form, and should comply with regulatory requirements and Section 4.2.10 Labelling of Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), including listing of ingredients and instructions on the handling, storing and use. All claims made on a label should be able to be substantiated.

9. Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by i*importing countries*, *Competent Authorities* contribute through the inspection or through the auditing of animal and public health activities conducted by other agencies or the private sector.

Feed and feed ingredients business operators and other relevant parts of industry should practice self-regulation to secure compliance with required standards for procurement, handling, storage, processing, distribution and use. Operators have full responsibility for implementing systems for quality control. The *Competent Authority* should verify that process control systems and safety standards achieve all regulatory requirements.

10. Assurance and certification

Feed business operators are responsible for demonstrating the safety of the establishments under their control. *Competent Authorities* are responsible for providing assurances domestically and to trading partners that regulatory safety standards have been met. For *international trade* in animal product based feeds, *Veterinary Services* are required to provide *international veterinary certificates*.

11. Hazards associated with animal feed

a) Biological hazards

Biological hazards that may occur in feed and feed ingredients include agents such as bacteria, viruses, prions, fungi and parasites.

EU comment

In the paragraph above "harmful botanical impurities" should be added. Indeed, these impurities may contain chemical or physical hazards but are biological (e.g. toxic seeds).

b) Chemical hazards

Chemical hazards that may occur in feed and feed ingredients include naturally occurring chemicals (such as mycotoxins and gossypol), industrial and environmental contaminants (such as dioxins and PCBs), residues of veterinary drugs and pesticides and also radionuclides.

c) Physical hazards

Physical hazards that may occur in feed and feed ingredients include foreign objects (such as pieces of glass, metal, plastic or wood).

12. Contamination

Procedures to minimise the risk of contamination during the ~~manufacture~~ production, processing, storage, distribution (including transport) and the use of feed and feed ingredients should be included in current regulations and standards. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

Procedures, such as flushing, sequencing and physical clean-out, should be used to reduce the likelihood of contamination between batches of feed or feed ingredients.

13. Antimicrobial resistance

Concerning the use of antimicrobials in animal feed refer to Chapters 6.7. to 6.10. of the *Terrestrial Code*.

14. Management of information

The *Competent Authority* should establish clear requirements for the provision of information by the private sector as this relates to regulatory requirements.

Records should be maintained in a readily accessible form regarding the production, distribution and use of feed and feed ingredients. These records are required to facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source, and trace-forward to the next subsequent recipients, to address identified animal health or public health concerns (see Section 4.3. of CAC/RCP 54-2004).

Animal identification and *animal traceability* are tools for addressing animal health (including *zoonoses*), and food safety risks arising from animal feed (see Chapters 4.1. and 4.2. of the *Terrestrial Code*).

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– text deleted

Annex XI

CHAPTER 5.X.

CONTROL OF OIE LISTED DISEASES IN HEAT TREATED, SHELF STABLE PET FOOD

EU comment

The EU is not opposed in principle to the inclusion of a new chapter concerning pet food in section 5 of the Code, but has some concerns regarding the proposed version.

Indeed, first of all the title seems to indicate that it deals with disease control, which is already taken care of in sections 6 and the specific diseases chapters. In fact, the whole chapter is unnecessary if its objective is to address animal and public health matters.

Concerning the text itself, in the article 2 point 2 there is an inconsistency in the first sentence, which could lead to serious misunderstanding and trade problems: the ingredients or products, whatever the treatment applied, should always comply with the relevant recommendations of the Code chapters. The EU strongly opposes to this sentence and would refuse any chapter that would include it.

The EU also insists that there should not be a double standard in the Code. Thus the table 1 "Risk mitigation measures for processing of pet foods containing ingredients of animal origin" in article 5.X.3, if kept, should not refer to other reference than existing articles in the relevant Code chapters. In any case, since these chapters already indicate minimum treatments depending on the products, the proposed Table 1 should in fact be deleted and replaced with a simple table that indicates the minimum time and temperature treatments applied to the ingredients of animal origin during the processing of heat treated, shelf stable pet food, as proposed in the former version. As this is the essential part and motivation of the proposed new chapter, it will only be ready for adoption when the table is presented filled with data. Until then, the chapter should not be proposed for adoption, and if it is not possible, it should simply be abandoned.

As an alternative, in order to avoid any problem of interpretation, it might be better to present this chapter as a new model certificate specific for the pet food, using the available templates in article 5.10.4, where an empty table would be inserted, in order to be filled by the exporting country.

Article 5.X.1.

Objective and scope

The objective of this chapter is to provide specific guidance on preventing the transfer of OIE listed diseases (Chapter 1.2.) through international trade in pet food. The chapter should be read in conjunction with Chapter 6.3. of the *Terrestrial Code*.

Pet food means any commercial feed prepared and distributed for consumption by dogs or cats. This chapter refers to heat-treated, shelf stable pet food (hereafter referred to as pet food). The finished product, in an unopened container, can exist at room temperature for an extended time period.

The chapter aims at ensuring the control of OIE listed diseases through adherence to recommended measures during the production pet food, including pet treats (snacks) and pet chews.

For the purpose of this chapter, "pets" are limited to dogs or cats.

Article 5.X.2.

Pet food specific measures

An important consideration with pet food is that ingredients from multiple animal species, often sourced from multiple countries, zones or compartments are combined into the final product. However, as the products covered in this chapter have been heat-treated, the products themselves would not pose significant animal health risk when compared to unprocessed products coming from the same countries, zones or compartments.

When determining the appropriate import requirements, the potential animal health concerns of all species and ingredients of animal origin need to be addressed.

The *Competent Authority* should take into account the following factors:

1. Sanitary measures should be based on the relevant chapters of the *Terrestrial Code* and according to the animal health status of the country, zone or compartment of origin of the animal-derived ingredients. The source of all animal-derived ingredients should be considered. All ingredients should meet OIE requirements, taking into account the end use.

2. When the ingredients cannot be certified as originating from a safe source, thermal treatment can be used for risk mitigation. The table in Article 3 can be used to determine the appropriate disease risk mitigation measures. These treatments should not be cumulative, only the most stringent treatment should apply and will address all identified animal health risks.

EU comment

The EU proposes to delete the first sentence of the point 2 above. It can induce misunderstanding and could be interpreted as contradictory to the point 1. The following sentence should then be modified as follows:

"The table in Article 3 indicates the minimum time / temperature treatments applied to ingredients of animal origin used in heat treated shelf stable pet food. They can be used to determine the appropriate disease risk mitigation measures in compliance with the recommendations of the relevant chapters of the *Terrestrial Code*.

3. Quality assurance in the processing facility should be sufficient to verify that the product has been treated as required. The facility should maintain processing records, and the system should provide alert if minimum processing is not accomplished.

4. After processing, the product should be handled in a manner designed to prevent contamination of finished product by unprocessed materials.

5. Processing facilities should have procedures in place to enable tracing and recall of non-compliant products.

Article 5.X.3.

Elimination of biological hazards from pet food

Biological hazards in pet food may be avoided or eliminated by a number of treatments such as those listed in Table 1. However, other processes determined to be equivalent should be accepted.

EU comment

The words "such as those listed in" should be deleted and replaced by the words "as required in the relevant chapters of the Code."

The following words should be added after "Table 1": "<u>indicates the minimum time / temperature treatments applied to ingredients of animal origin used in heat treated shelf stable pet food. They can be used in determining the compliance with the recommendations of the chapters.</u>"

Table 1. Risk mitigation measures for processing of pet foods containing ingredients of animal origin (under study)

Biological Hazard	Bovine	Ovine	Caprine	Porcine	Equine	Poultry	Egg	Milk
Bluetongue	NR (Article 8.3.2)	NR (Article 8.3.2)	NR (Article 8.3.2)	NR	NR	NR	NR	NR (Article 8.3.2)
Foot and mouth disease	70C/30min (Article 8.5.34.)				NR	NR	NR	(Article 8.5.28.)
Rift Valley fever					NR	NR	NR	
Rinderpest					NR	NR	NR	
Vesicular stomatitis	NR	NR	NR	NR	NR	NR	NR	NR
Avian influenza	NR	NR	NR	NR	NR	60C/507 sec 70C/3.5 sec 74C/0.51 sec (Article 10.4.26)	60C/188 sec (Article 10.4.25)	NR
Newcastle disease	NR	NR	NR	NR	NR	65C/14 min 74C/5 min (Article 10.13.21)	57C/26.6 min (Article 10.13.20)	NR
Infectious bursal disease	NR	NR	NR	NR	NR			NR
Bovine spongiform encephalopathy	Safe commodities (Article 11.6.1)	NR	NR	NR	NR	NR	NR	NR
Contagious bovine pleuropneumonia	(Article 11.8.2)	NR	NR	NR	NR	NR	NR	NR
African horse sickness	NR	NR	NR	NR	NR	NR	NR	NR
Pest des petits ruminants	NR			NR	NR	NR	NR	NR
African swine fever	NR	NR	NR		NR	NR	NR	NR
Classical swine fever	NR	NR	NR	70c/internal pH<6 (Article 15.2.21)	NR	NR	NR	NR
Swine vesicular disease	NR	NR	NR		NR	NR	NR	NR

NR means no sanitary measures should be imposed.

EU comment

Table 1 above should be deleted and replaced with the former version of the table, <u>filled with data</u>.

Table 1. Minimum time and temperature treatments for processing of pet foods containing ingredients of animal origin

Group	**Subgroup**	**Minimum time and temperature treatments**
A - Wet	**1) Low-acid in hermetically sealed containers** **2) Refrigerated pet food in non-hermetically sealed containers**	**1) F_0= 3** **F_c= 3** **2)**

B - Soft Moist	**1)**	**Extruded-expanded**	**1)**
	2)	**Extruded-non-expanded**	**2)**
	3)	**Non-extruded**	**3)**

C - Dry	**1)**	**Extruded-expanded**	**1)**
	2)	**Extruded non-expanded**	**2)**
	3)	**Non-extruded**	**3)**

Annex XII

CHAPTER 6.4.

BIOSECURITY PROCEDURES IN POULTRY PRODUCTION

EU comment

The EU can support the proposed changes but has one comment.

Article 6.4.1.

Introduction

This chapter provides recommended biosecurity procedures in *poultry* production and is not specifically related to trade.

Infectious ~~*disease*~~ agents of *poultry* are a threat to *poultry* health and, at times, human health and have significant social and economic implications. In *poultry* production, especially under intensive conditions, prevention is the most viable and economically feasible approach to the control of infectious ~~*disease*~~ agents.

Biosecurity procedures should be implemented with the objective of preventing the introduction and dissemination of infectious ~~*disease*~~ agents in the *poultry* production chain. Biosecurity will be enhanced with ~~T~~the adoption and implementation of the principles of Good Agricultural Practices and the Hazard Analysis Critical Control Point (HACCP) system ~~will help to achieve these objectives~~.

Article 6.4.2.

Purpose and scope

This chapter deals with biosecurity procedures in *poultry* production. It should be read in conjunction with the Codex Alimentarius Code of Hygiene~~ne~~ic Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976 ~~Revision 2007~~).

~~This chapter provides general recommendations for infectious *disease* agents of *poultry*.~~ ~~Recommendations on specific *diseases* may be found in relevant *disease* chapters in the *Terrestrial Code*.~~

This chapter identifies several ~~relevant~~ biosecurity measures. The choice of measures to be implemented will vary according to national conditions, including *poultry* ~~*disease*~~ *infection* status, the risk of introduction and dissemination of infectious ~~*disease*~~ agents and the cost effectiveness of control measures.

Recommendations on specific infectious agents may be found in relevant *disease* chapters in the *Terrestrial Code.*

Article 6.4.3.

Definitions ~~(for this Chapter only)~~

Breeders: means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing *day-old birds*.

~~**Culling:** means the depopulation of a *flock* before the end of its normal production period.~~

Live bird markets: means markets where live birds from various sources are sold for *slaughter*, ~~or~~ further rearing or production.

Article 6.4.4.

Recommendations on the location and construction of poultry establishments

1. All establishments (poultry farms and hatcheries)

   a) A suitably isolated geographical location is recommended, ~~taking into account~~ Factors to consider include the ~~direction of the prevailing winds,~~ location of other *poultry* and livestock *establishments*, wild bird concentrations and the distance from roads used to transport *poultry*.

   b) *Poultry establishments* should be located and constructed to provide adequate drainage ~~away from~~ for the site. Run-off or untreated site wastewater should not discharge into waterfowl habitats.

   c) *Poultry* houses and hatcheries should be designed and constructed (preferably of smooth impervious materials) so that cleaning and *disinfection* can be carried out effectively. Ideally, the area immediately surrounding the *poultry* houses and hatcheries should be paved with concrete or other impervious material to facilitate cleaning and *disinfection*.

   d) The *establishment* should be surrounded by a security fence to prevent the entry of unwanted animals and people.

   e) A sign indicating restricted entry should be posted at the entrance to the ~~farm~~ *establishment*.

2. Additional measures for poultry farms

   a) *Establishments* should be designed ~~for use with~~ to house a single species and a single production type ~~purpose~~. ~~Whenever possible,~~ ~~t~~The design should also consider the 'all-in all-out' single age group principle ~~should be used~~. If this is not feasible ~~and several *flocks* are maintained on one *establishment*~~, the *establishment* should be designed so that each *flock* can ~~should~~ be managed as a separate *epidemiological unit*.

   b) *Poultry* houses, and buildings used to store feed, ~~or~~ eggs~~,~~ or other material, should be constructed and maintained to prevent the entry of wild birds, rodents and ~~insects~~ arthropods.

   c) Where feasible, the floors of *poultry* houses should be constructed using concrete or other impervious materials and designed so that cleaning and *disinfection* can be carried out effectively.

   d) Where feasible, feed should be delivered into the farm from outside the security fence.

3. Additional measures for hatcheries

   a) The design of the hatchery should take account of work flow and air circulation needs, with 'one way flow' movement of eggs and *day-old birds* and one way air flow in the same direction.

   b) The hatchery buildings should include physical separation of areas used for the following:

      i) personnel changing, showering and sanitary facilities;

      ii) receipt, storage and transfer of eggs;

iii) incubation;

iv) hatching;

v) sorting, sexing and other handling ~~placing~~ of *day-old birds* ~~in boxes~~;

vi) storage of egg boxes and ~~chick~~ boxes for *day-old birds*, egg flats, chick box ~~pads~~ liners, chemicals and other items;

vii) ~~washing~~ equipment washing;

viii) waste disposal;

ix) dining facilities for personnel;

x) office space.

Article 6.4.5.

Recommendations applicable to the operation of poultry establishments

1. All establishments (poultry farms and hatcheries)

a) All *establishments* should have a written biosecurity plan. Personnel in the *establishments* should have access to basic training in biosecurity relevant to *poultry* production and understand the implications to animal health, human health and food safety.

~~a)~~b) There should be good communication between ~~all those~~ personnel involved in the *poultry* production chain ~~from breeding to production and consumption~~ to ensure that steps are taken to minimise the introduction and dissemination of infectious ~~*disease*~~ agents. ~~Personnel should have access to basic training in biosecurity relevant to *poultry* production and food safety.~~

~~b~~c) Traceability at all levels of the *poultry* production chain should be possible.

~~c~~d) Records ~~of production~~ should be maintained~~.~~ on an individual *flock* basis and include data on bird health, production, ~~On farm, this includes~~ cleaning and *disinfection*, ~~treatment~~ medications, vaccination, ~~*flock* history,~~ mortality and ~~*disease surveillance* data~~. ~~This should be maintained on an individual *flock* basis.~~ In hatcheries, ~~relevant~~ records should include data on fertility, hatchability, vaccination and treatments. Records should be readily available for inspection on site.

~~d~~e) ~~A veterinarian should be responsible for m~~Monitoring of *poultry* health on the *establishment* should be under the supervision of a *veterinarian*.

~~e~~f) ~~Access to the *establishment* should be controlled to ensure only authorised persons and *vehicles* enter the site.~~

~~g~~f) *Establishments* should ~~be free from~~ control unwanted vegetation and be free from debris.

~~g~~h) Procedures for the prevention of entry of wild birds into *poultry* houses and buildings, and the control of vermin such as rodents and arthropods should be implemented ~~on a routine basis~~.

i) Access to the *establishment* should be controlled to ensure only authorised persons and *vehicles* enter the site.

~~h~~i) All personnel and visitors entering an *establishment* should follow a biosecurity procedure. The preferred procedure is for visitors and personnel entering the *establishment* to shower and change into clean clothes and footwear provided by the *establishment*. Where this is not practical, clean outer garments (coveralls or overalls, head covering ~~hats~~ and footwear) should be provided.

~~Before entering and after leaving a *poultry* house, personnel and visitors should wash their hands with soap and water use a properly maintained disinfectant footbath. The disinfectant solution in the footbath should be changed on a regular basis to ensure its efficacy, according to the manufacturer's instructions.~~

~~i~~j) Personnel and visitors should not have had recent contact with other *poultry*, *poultry* waste, or *poultry* processing plant(s). This time period should be based on the level of risk of transmission of infectious ~~*disease*~~ agents. This will depend on the *poultry* production purpose, biosecurity procedures and ~~*disease*~~ *infection* status (e.g. the time between visiting a breeder *flock* and then a broiler *flock* would be less than the time between visiting a broiler *flock* and then a breeder *flock*).

~~j~~k) Delivery *vehicles* should be cleaned, and *disinfected* before loading each consignment of ~~*hatching*~~ eggs~~, *day old birds*~~ or *poultry*.

2. Additional measures for all poultry farms

a) Whenever possible, the 'all-in all-out' single age group principle should be used. If this is not feasible and several *flocks* are maintained on one *establishment*, each *flock* should be managed as a separate *epidemiological unit.*

b) All personnel and visitors entering a *poultry* house should wash their hands with soap and water or sanitize them using a disinfectant. Personnel and visitors should also change footwear, use a boot spray or use a properly maintained disinfectant footbath. The disinfectant solution in the footbath should be changed on a regular basis to ensure its efficacy, according to the manufacturer's instructions.

c) Animals, other than *poultry* of the appropriate (resident) species and age, should not be permitted access to *poultry* houses. No animals should have access to other buildings (e.g. those used to store feed, ~~or~~ eggs or other material).

~~b~~d) The drinking water supply to *poultry* houses should be potable according to the World Health Organization or to the relevant national standard, and microbiological quality should be monitored if there is any reason to suspect contamination. The water delivery system should be cleaned and *disinfected* between *flocks* when the *poultry* house is empty.

~~c~~e) Birds used to stock a *poultry* house should preferably be obtained from breeder *flocks* and hatcheries that are free from vertically transmitted infectious ~~*disease*~~ agents.

~~d~~f) Heat treated feeds with or without the addition of other bacteriocidal~~static~~ or bacteriostatic~~cidal~~ treatments (e.g. addition of organic acids) ~~is~~ are recommended ~~(e.g. organic acids)~~. Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended.

EU Comments

The use of antibiotics should not be recommended in the feed, so the words ", but not antibiotics" should be added after the words "organic acids".

Feed should be stored in a manner to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents. The movement of feed between *flocks* should be avoided.

~~e~~g) The litter in the *poultry* house should be kept dry and in good condition.

~~f~~h) Dead birds should be removed from *poultry* houses as quickly as possible but ~~or~~ at least daily. These should be disposed of in a safe and effective manner.

~~g~~i) Personnel involved in the catching of birds should be adequately trained in bird handling and basic biosecurity procedures.

~~h~~i) To minimise stress *p~~P~~oultry* should be transported in well ventilated *containers* and should not be over crowded. Exposure to extreme temperatures should be avoided.

~~i~~k) *Containers* should be *cleaned* and *disinfected* between each use.

~~j~~l) When a *poultry* house is depopulated, it is recommended that all faeces and litter be removed from the house and disposed of in a safe manner to minimise the risk of dissemination of infectious agents ~~approved by the *Veterinary Services*~~.

If litter is not removed and replaced between *flocks* then the litter should be treated in a manner to ~~inactivate infectious *disease* agents, to prevent~~ minimise the risk of dissemination of infectious ~~*disease*~~ agents from one *flock* to the next.

After removal of faeces and litter, cleaning and *disinfection* of the *poultry* house ~~building~~ and equipment should be done in accordance with Chapter 4.13.

~~All litter removed from a *poultry* house should be disposed of in a safe manner to prevent the dissemination of infectious agents.~~

~~k~~m) For *poultry flocks* that are allowed to range outdoors, feeders, feed and other items which may attract wild birds should be kept indoors. ~~attractants to wild birds should be minimised e.g. feeders should be kept inside the poultry house~~. *Poultry* should not be allowed access to sources of contamination (e.g. household waste, litter storage areas, other ~~farm~~ animals, stagnant water and water of unknown quality ~~and litter storage areas~~). The nesting area should be inside the *poultry* house.

~~l~~n) To avoid the development of antimicrobial resistance, antimicrobials should be used according to relevant directions of the *Veterinary Services* and manufacturer's instructions and in accordance with *Terrestrial Code* Chapters 6.8, 6.9., 6.10. and 6.11.

3. Additional measures for layers

Refer to Section 3 of the Codex Alimentarius Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976).

~~3~~4. Additional measures for breeders ~~farms~~

a) Nest box litter and liners should be kept clean.

b) *Hatching eggs* should be collected at frequent intervals, at least daily, and placed in ~~a~~ new or clean and *disinfected* packaging material.

c) Grossly dirty, ~~broken,~~ cracked, broken, or leak~~er~~ing eggs should be collected separately and should not be used as *hatching eggs*.

d) *Hatching eggs* should be cleaned and sanitized as soon as possible after collection using an approved sanitising agent, in accordance with the manufacturer's instructions.

e) *Hatching eggs* or their packaging materials should be marked to assist traceability and veterinary investigations.

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f) The ~~sanitised~~ *hatching eggs* should be stored in a dedicated room as soon as possible after cleaning and sanitisation ~~collection~~. Storage conditions should minimise the potential for microbial contamination and growth and ensure maximum hatchability. The room should be well ventilated, kept clean, and regularly *disinfected* using disinfectants approved for this purpose.

~~4~~5. Additional measures for hatcheries

a) Dead in shell embryos should be removed from hatcheries as soon as they are found and disposed of in a safe and effective manner.

b) All hatchery waste, garbage and discarded equipment should be contained or at least covered while on site and removed from the hatchery and its environs as soon as possible.

c) After use, hatchery equipment, tables and surfaces should be promptly and thoroughly cleaned and *disinfected* with an approved disinfectant.

d) Egg handlers, ~~chick~~ sexers and ~~chick~~ handlers of *day-old birds* should wash their hands with soap and water before commencing work and between working with batches of *hatching eggs* or *day-old birds* from different breeder *flocks*.

e) *Hatching eggs* and *day-old birds* from different breeder *flocks* should be ~~kept separate~~ identifiable during incubation, hatching, sorting and transportation.

f) *Day-old birds* should be delivered to the farm in new *containers* or in clean, *disinfected containers*.

Article 6.4.6.

Prevention of further dissemination of infectious ~~disease~~ agents of poultry

When a *flock* is suspected to be infected or determined to be infected, in addition to the general biosecurity measures described previously, management procedures should be adjusted to effectively isolate ~~the infected *flock*~~ it from other *flocks* on the *establishment* and other epidemiologically related *establishments*. The following measures are recommended:

1. Personnel should ~~be trained in the~~ manage~~ment of~~ suspected or infected *flocks* to ~~prevent~~ minimise the risk of ~~the~~ dissemination of infectious ~~*disease*~~ agents to other *flocks* and *establishments*, and to humans. ~~(~~Relevant measures include~~:~~ handling of an infected *flock* separately, last in sequence and the use of dedicated personnel, ~~and~~ clothing and equipment~~)~~.

2. A veterinarian should be consulted immediately.

3. When *infection* has been confirmed, e~~E~~pidemiological investigations should be carried out to determine the origin and route of transmission of the infectious ~~*disease*~~ agent.

~~3~~4. *Poultry* litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to ~~prevent~~ minimise the risk of dissemination of infectious ~~*disease*~~ agents. The disposal method used will depend on the infectious agent involved.

~~4~~5. Depending on the epidemiology of the ~~*disease*~~ infectious agent, the results of a *risk assessment*, and public and animal health policies, ~~culling~~ destruction or *slaughter* of a *flock* before the end of the normal production period may be used ~~to manage infected *flocks*~~. When infected *flocks* are destroyed or *slaughtered* they should be processed in a manner to minimise exposure of humans and other *flocks* to the infectious ~~*disease*~~ agent, and in accordance with recommendations of the *Veterinary Service* and relevant Chapters in the *Terrestrial Code*. Based on *risk assessment*, non-infected, high risk *flocks* may be ~~culling~~ destroyed or *slaughtered* before the end of their normal production period~~. Movement of culled *poultry* should only be allowed for *slaughter* or destruction.~~

Before restocking, the *poultry* house including equipment ~~or *establishment*~~ should be cleaned, *disinfected* and tested to verify that the cleaning has been effective. Special attention should be paid to feed equipment and water systems.

Microbiological monitoring of the efficacy of *disinfection* procedures is recommended when pathogenic agents have been detected in the previous *flock*.

~~5~~6. Depending on the epidemiology of the ~~*disease*~~ infectious agent, *risk assessment*, vaccine availability and public and animal health policies, vaccination is an option to minimise the dissemination of the infectious ~~*disease*~~ agent. When used, vaccines ~~*poultry*~~ should be administered ~~vaccinated~~ in accordance with the directions of the *Veterinary Services* and the manufacturer's instructions. Recommendations in the *Terrestrial Manual* should be followed as appropriate.

Article 6.4.7.

Recommendations to prevent the dissemination of infectious ~~disease~~ agents to and from live bird markets

1. Personnel should be educated on the significance of infectious ~~*disease*~~ agents and the need to apply biosecurity practices to prevent dissemination of these agents. Education should be targeted to personnel at all levels of operations in these markets (e.g. drivers, owners, handlers, processors).

   Programmes should be implemented to raise consumer awareness ~~of consumers~~ about ~~of~~ the risks associated with activities of live bird markets

2. Personnel should wash their hands with soap and water before and after handling birds.

3. Birds from diseased *flocks* should not be transported to live bird markets.

~~3~~4. All *containers* and *vehicles* should be cleaned and *disinfected* every time they leave the market.

~~4~~5. Live birds that leave the market and go to a farm should be ~~housed~~ kept separately from other birds for a period of time to minimise the potential dissemination of infectious ~~*disease*~~ agents of *poultry*.

~~5~~6. Periodically the market should be emptied, cleaned and *disinfected*. This is of particular importance when an infectious ~~*disease*~~ agent of *poultry* deemed significant by the *Veterinary Services* has been identified in the market or the region.

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~~6~~7. Where feasible, *surveillance* should be carried out in these markets to detect infectious ~~*disease*~~ agents of *poultry*~~, especially those agents of zoonotic significance~~. The *surveillance* programme should be determined by the *Ve~~r~~terinary Services*, and in accordance with recommendations in relevant ~~*disease* specific~~ chapters of the *Terrestrial Code*.

~~7~~8. ~~Attempts~~ Efforts should be made to ensure the possibility of tracing all birds entering and leaving the markets.

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— text deleted

CHAPTER 6.5.

PREVENTION, DETECTION AND CONTROL OF *SALMONELLA* IN POULTRY

EU comment

The EU can support the proposed changes but has one comment.

Article 6.5.1.

Introduction

This Chapter provides recommendations on the prevention, detection and control of *Salmonella* in *poultry*.

Salmonellosis is one of the most common foodborne bacterial *diseases* in the world. The great majority of *Salmonella infections* in humans are foodborne with *Salmonella* Enteritidis and *Salmonella* Typhimurium accounting for a major part of the problem. *Salmonella* serotypes and prevalence may vary considerably between localities, districts, regions and countries and therefore, *surveillance* and identification of the prevalent *Salmonella* serotypes in humans and *poultry* should be carried out in order to develop a control programme for the area.

In most food animal species, *Salmonella* can establish a clinically inapparent *infection* of variable duration, which is significant as a potential *zoonosis*. Such animals may be important in relation to the spread of *infection* between *flocks* and as causes of human foodborne *infection*. In the latter case, this can occur when *meat* and eggs, or their products, enter the food chain thus producing contaminated food.

Article 6.5.2.

Purpose and scope

This Chapter deals with methods for on farm prevention, detection and control of *Salmonella* in *poultry*, and complements the Codex Alimentarius Code of Hygien~~e~~ic Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976). A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in reducing the presence of foodborne pathogens in eggs and *meat*.

Hygiene and biosecurity procedures to be implemented in *poultry ~~flocks~~* farms and hatcheries are described in Chapter 6.4. Hygiene and Biosecurity Procedures in Poultry Production.

The recommendations presented in this Chapter are relevant to the control of all *Salmonella* with special attention to *S*. Enteritidis and *S*. Typhimurium, as these are common *Salmonella* serotypes in many countries. It should be noted that the epidemiology of animal and human salmonellosis in a particular locality, district, region or country is important for effective control of *Salmonella*.

Article 6.5.3.

Definitions ~~(for this Chapter only)~~

Breeders: means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing *day-old birds*.

Competitive exclusion: means the administration of defined or undefined bacterial flora to *poultry* to prevent gut colonisation by enteropathogens, including *Salmonella*.

Culling: means the ~~depopulation~~ destruction or *slaughter* of a *flock* before the end of its normal production period.

Layers: means *poultry* during the period of laying eggs for human consumption.

Article 6.5.4.

Surveillance of poultry flocks for *Salmonella*

Where justified by *risk assessment*, *surveillance* should be carried out to identify infected *flocks* in order to take measures that will reduce the prevalence in *poultry* and the risk of transmission of *Salmonella* to humans. Sampling methods, frequency and type of samples required should be determined by the *Veterinary Services* based on a *risk assessment*. Microbiological testing is preferred to serological testing because of its higher sensitivity in broilers ~~s~~ *flocks* and higher specificity in breeders and *layer flocks*. In the framework of regulatory programmes for the control of *Salmonella* in *poultry* and salmonellosis in humans, confirmatory testing may be required.

Sampling

1. Available methods for sampling

   Drag swabs: sampling is done by dragging swabs throughout the *poultry* ~~building~~ house.

   Boot swabs: sampling is done by walking throughout the *poultry* ~~building~~ house with absorbent material placed over the footwear of the sampler.

   Dust samples: sampling is done by collecting dust from exhaust fans, screens and other equipment in the *poultry* ~~building~~ house.

   Faecal samples: multiple fresh faecal/caecal samples collected from different areas in the *poultry* ~~building~~ house.

   Meconium, chick box liners ~~papers~~, dead in shell and culled ~~chicks~~ *day-old birds* at the hatchery.

   Hatchery samples: throughout the hatchery, including inside the incubators.

2. Sample size

   Refer to the *Terrestrial Manual* (under development).

3. Laboratory methods

   Refer to the *Terrestrial Manual* (under development).

4. Time and frequency of testing

   Time and frequency of sampling for each *poultry* type are listed below:

a) Breeders and hatcheries

i) Breeder flocks before lay

- Before the end of the first week of life when the status of the breedering *flock* ~~farm~~ ~~and/~~or the hatchery is not known or does not comply with this chapter.
- Within the four weeks before being moved to another house, or before going into production if the birds will remain in the same house for the production period.
- One or more times during the growing period if there is a culling policy in place. The frequency would be determined on commercial considerations.

ii) Breeder flocks in lay

- At least at monthly intervals during the laying period.
- Additional testing should be determined by the *Veterinary Services*.

iii) Hatcheries

- Testing at hatcheries should complement on farm testing.
- The minimal frequency should be determined by the *Veterinary Services*.

b) Poultry for the production of eggs for human consumption

i) Flocks grown to be layers

- Before the end of the first week of life when the status of the breedering *flock* ~~farm~~ ~~and/~~or the hatchery is not known or does not comply with this chapter.
- Within the four weeks before being moved to another house, or before going into production if the birds will remain in the same house for the production period.
- One or more times during the growing period if there is a culling policy in place. The frequency would be determined by commercial considerations.

ii) Layer flocks

- At expected peak of lay for each production cycle (the period of time in the laying cycle when the production of the *flock* is highest).
- One or more times if there is a culling policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency should be determined by the *Veterinary Services*.

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c) Poultry for the production of meat

i) *Flocks* should be sampled at least once ~~before *slaughter.*~~

ii) When sampling occurs on farms and when there is a long period (2 weeks or more) between thinning and final depopulation further testing should be considered.

iii) When sampling occurs on farms, *flocks* should be sampled as late as possible before the first birds are transported to the *slaughterhouse*. In order to allow for the implementation of control measures during processing, this should be done at a time that ensures the results are available before *slaughter*.

Whether sampling occurs on the farm which is more appropriate for consequent control measures or at the processing plant, there should be an integrated system in place that allows for investigation of the source of positive *flocks*.

d) Testing of c~~E~~mpty ~~building~~ poultry houses ~~testing~~

i) Bacteriological monitoring of the efficacy of *disinfection* procedures is recommended when *Salmonella* have been detected in the previous *flock*.

As appropriate, sampling of equipment and surfaces as well as boot swabs or drag swabs of the empty ~~building~~ *poultry* house after depopulation, cleaning and *disinfection*.

Results from *surveillance* may lead to the implementation of additional prevention and control measures to reduce the risk of transmission of *Salmonella* to humans:

a) In breeders, control measures may be implemented to reduce the transmission of *Salmonella* to the next generation, especially for trans-ovarian transmitted serotypes such as *S*. Enteriditis.

b) In *layer flocks* control measures will reduce and may eliminate contamination of eggs with *Salmonella*.

c) In *poultry* for *meat* production, control measures may be implemented at *slaughter* or further down the food chain.

Article 6.5.5.

Prevention and Control measures

Salmonella prevention and control may be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP), and general measures detailed in Chapter 6.4. Hygiene and Biosecurity Procedures in Poultry Production, in combination with the following additional measures, where appropriate. No single measure used alone will achieve effective *Salmonella* control.

Additional prevention and control measures include: vaccination, competitive exclusion, ~~*flock* culling,~~ use of organic acids, culling and product diversion to processing.

Antimicrobials should not be used to control *infection* with *Salmonella* in *poultry* because the effectiveness of the treatment is limited, may mask the infection at sampling, has the potential to produce residues in *meat* and eggs and can contribute to the development of antimicrobial resistance. Antimicrobials may also reduce normal flora in the gut and increase the likelihood of colonisation with *Salmonella*. In special circumstances antimicrobials may be used to salvage birds with high genetic value.

1. *Day-old birds* used to stock a *poultry* house should be obtained from breedering *flocks* and hatcheries that have been monitored according to this Chapter and in which no evidence of *S*. Enteritidis and *S*. Typhimurium has been detected.

2. *Layer* and breeder *flocks* should be stocked from *flocks* that have been monitored according to this chapter and in which no evidence of *S*. Enteritidis and *S*. Typhimurium has been detected.

3. Feed contamination with *Salmonella* is known to be a source of *infection* for *poultry*. Therefore, it is recommended to monitor the *Salmonella* status of *poultry* feed, and if found positive to take corrective measures.

   The use of hHeat treated feeds with or without the addition of or feeds subjected to other bacteriocidalstatic or bacteriostaticcidal treatments (e.g. addition of organic acids). (e.g. organic acids) is are recommended (e.g. organic acids). Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended.

EU Comments

The use of antibiotics should not be recommended in the feed, so the words ", but not antibiotics" should be added after the words "organic acids".

   Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.

4. Competitive exclusion may be used in *day-old birds* to reduce colonisation by *Salmonella*.

   When used, competitive exclusion should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

5. Vaccines are used against *Salmonella infections* caused by different serotypes in various *poultry* species, including single or combined vaccines. Vaccines produced according to the *Terrestrial Manual* should be used.

   If live vaccines are used it is important that field and vaccine strains be easily differentiated in the laboratory. If serology is used as the *surveillance* method, it may not be possible to distinguish between vaccination and *infection* with a field strain.

   Vaccination can be used as part of an overall *Salmonella* control programme. It is recommended that vaccination not be used as the sole control measure.

   When the status of the breedering *flock* farm and/or the hatchery from which the *flock* originates is not known or does not comply with this Chapter, vaccination of *flocks*, starting with *day-old birds*, against the *Salmonella* serotypes known to be significant should be considered.

   Vaccination against the *Salmonella* serotypes known to be significant should be considered when moving *day-old birds* to a previously contaminated shed so as to minimise the risk of the birds contracting *Salmonella infection*.

   When used, vaccines should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

   Vaccination against *S*. Enteritidis can cause cross reactions in *Salmonella* Pullorum/*S*. Gallinarum serological tests and needs to be considered when implementing measures for these pathogens.

6. Depending on animal health, *risk assessment*, and public health policies, culling is an option to manage infected breeder and *layer flocks*. Infected *flocks* should be destroyed or *slaughtered* and processed to minimise human

exposure to *Salmonella*.

If culling is not applied ~~*poultry* are not culled~~, eggs for human consumption should be diverted for processing for inactivation of *Salmonella*.

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7. *S*. Enteritidis is characterised by its ovarian transmission pattern. Countries should set targets for eradicating (or significantly reducing) *S*. Enteritidis from egg-producing *flocks* through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent *flocks* through breeder *flocks* to *layer flocks*.

8. The responsible *veterinarian* should evaluate the results of *surveillance* testing for *Salmonella* and supervise the implementation of appropriate control measures. ~~This information~~ These results should be available to the veterinarian before marketing if a veterinary certificate for *flock Salmonella* status is required. When required by the *Competent Authority*, the veterinarian or other person responsible for notification should notify the *Competent Authority* if the presence of *Salmonella* of the relevant serotype is confirmed.

Article 6.5.6.

Prevention of *Salmonella* spread from infected flocks

If a *flock* is found infected with specific *Salmonella* serotypes of concern, the following actions should be taken in addition to general measures detailed in Chapter 6.4. Hygiene and Biosecurity Procedures in Poultry Production:

1. According to the epidemiological situation, investigations should be carried out to determine the origin of the *infection*.

2. Movement of *poultry flocks* at the end of the production cycle should only be allowed for *slaughter* or destruction. Special precautions should be taken in the transport, *slaughter* and processing of the birds, e.g. they could be sent to a separate *slaughterhouse* or processed at the end of a shift before cleaning and *disinfection* of the equipment.

3. Litter should not be reused. *Poultry* litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the direct or indirect exposure of humans, livestock and wildlife to *Salmonella*. Particular care needs to be taken in regard to *poultry* litter/faeces used to fertilise plants intended for human consumption. If litter is not removed then it should be treated in a manner to inactivate infectious agents, to prevent the spread from one *flock* to the next.

4. Particular care should be taken in cleaning and *disinfection* of the *poultry* house and equipment.

5. Before restocking the facility, a bacteriological examination should be carried out as detailed in this Chapter and the *Terrestrial Manual*.

Article 6.5.7.

Recommendations for importation of live poultry (other than day-old birds)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* originated from a~~n establishment~~ *flock* that participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;

2. the *poultry* originated from a~~n establishment~~ *flock* in which no evidence of *S*. Enteritidis and *S*. Typhimurium has been detected prior to shipment and have had no contact with birds or other material from ~~establishment~~ *flocks*

that do not comply with this chapter;

3. the *poultry* originated from a~~n~~ ~~*establishment*~~ *flock* that complies with the recommendations of Chapter 6.4.

Article 6.5.8.

Recommendations for importation of day-old birds

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *day-old birds* showed no clinical signs of salmonellosis on the day of shipment;

2. the *day-old birds* originated from a breeder ~~*establishment*~~ *flock* and hatchery that participate in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;

3. the *day-old birds* originated from a breeder ~~*establishment*~~ *flock* and hatchery in which no evidence of *S*. Enteritidis and *S*. Typhimurium has been detected and have had no contact during setting, incubation or hatching with *hatching eggs* or other material from an *establishment* that do not comply with this chapter;

4. the *day-old birds* originated from a breeder ~~*establishment*~~ *flock* and hatchery that complies with the recommendations of Chapter 6.4.;

5. the *day-old birds* were shipped in new and clean *containers*.

Article 6.5.9.

Recommendations for importation of hatching eggs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *hatching eggs* originated from a breeder ~~*establishment*~~ *flock* that participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;

2 the *hatching eggs* originated from a breeder ~~*establishment*~~ *flock* in which no evidence of *S*. Enteritidis and *S*. Typhimurium has been detected and have had no contact with *poultry* or other material from an *establishments* that do not comply with this Chapter;

3. the *hatching eggs* originated from a breeder ~~*establishment*~~ *flock* that complies with the recommendations of Chapter 6.4.;

4. the *hatching eggs* were shipped in new and clean packaging materials.

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Annex XIIII

CHAPTER 7.3.

TRANSPORT OF ANIMALS BY LAND

EU comment

The EU acknowledges the work carried out by the OIE to address specific requirements for the transport of poultry and supports the proposed changes.

Moreover, the EU thanks the OIE for having taken into account previous EU comments.

Some previous EU comments are reiterated given their importance to maintain proper welfare for the animals during transport.

Preamble: These recommendations apply to the following live domesticated *animals*: cattle, buffaloes, camels, sheep, goats, pigs, *poultry* and equines. They will also be largely applicable to some other *animals* (e.g., deer, other camelids and ratites). Wild, feral and partly domesticated *animals* may need different conditions.

Article 7.3.1.

The amount of time *animals* spend on a *journey* should be kept to the minimum.

Article 7.3.2.

1. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns, which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in groups and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed.

The desire of some *animals* to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vessels* and *containers*.

Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans (i.e. tame) have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape and compromise the *welfare* of the *animals*.

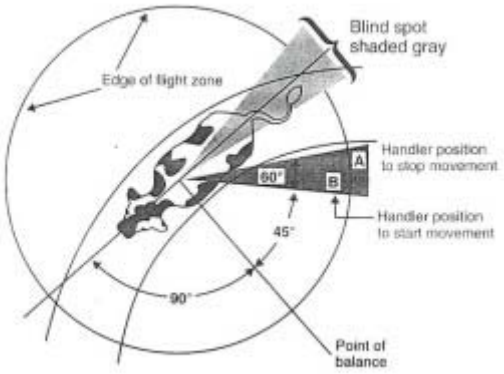
Animal handlers should use the point of balance at the *animal*'s shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

Domestic *animals* have a wide-angle vision but only have a limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

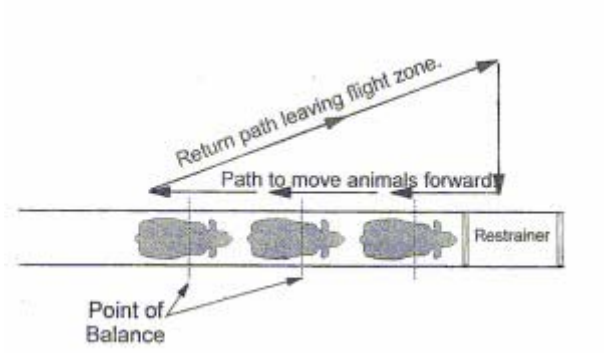
Although domestic *animals* have a highly sensitive sense of smell, they may react differently to the smells encountered during travel. Smells which cause negative responses should be taken into consideration when managing *animals*.

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noises and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



2. <u>Distractions and their removal</u>

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching *animals* to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors - move a lamp or change lighting;

b) dark entrances — illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals*;

c) *animals* seeing moving people or equipment up ahead — install solid sides on chutes and races or install shields;

d) dead ends — avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences — remove them;

f) uneven floors or a sudden drop in floor levels — avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;

g) sounds of air hissing from pneumatic equipment — install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

h) clanging and banging of metal objects — install rubber stops on gates and other devices to reduce metal to metal contact;

i) air currents from fans or air curtains blowing into the face of *animals* — redirect or reposition equipment.

Article 7.3.3.

Responsibilities

Once the decision to transport the *animals* has been made, the *welfare* of the *animals* during their *journey* is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this article.

The roles of each of those responsible are defined below:

1. The owners and managers of the *animals* are responsible for:

   a) the general health, overall *welfare* and fitness of the *animals* for the *journey*;

   b) ensuring compliance with any required veterinary or other certification;

   c) the presence of an *animal handler* competent for the species being transported during the *journey* with the authority to take prompt action; in case of transport by individual trucks, the truck driver may be the sole *animal handler* during the *journey*;

   d) the presence of an adequate number of *animal handlers* during *loading* and *unloading*;

   e) ensuring that equipment and veterinary assistance are provided as appropriate for the species and the *journey*.

2. Business agents or buying/selling agents are responsible for:

   a) selection of animals that are fit to travel;

   b) availability of suitable facilities at the start and at the end of the *journey* for the assembly; *loading*, transport, *unloading* and holding of *animals*, including for any stops at *resting points* during the *journey* and for emergencies.

3. *Animal handlers* are responsible for the humane handling and care of the *animals*, especially during *loading* and *unloading*, and for maintaining a *journey* log. To carry out their responsibilities, they should have the authority to take prompt action. In the absence of a separate *animal handler*, the driver is the *animal handler*.

4. Transport companies, *vehicle* owners and drivers are responsible for planning the *journey* to ensure the care of the *animals*; in particular they are responsible for:

a) choosing appropriate *vehicles* for the species transported and the *journey*;

b) ensuring that properly trained staff are available for *loading/unloading* of *animals*;

c) ensuring adequate competency of the driver in matters of *animal welfare* for the species being transported in case a separate *animal handler* is not assigned to the truck;

d) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;

e) producing a *journey* plan which includes a *loading* plan, *journey* duration, itinerary and location of *resting places*;

f) *loading* only those *animals* which are fit to *travel*, for their correct *loading* into the *vehicle* and their inspection during the *journey*, and for appropriate responses to problems arising; if its fitness to *travel* is in doubt, the *animal* should be examined by a *veterinarian* in accordance with point 3a) of Article 7.3.7.;

g) *welfare* of the *animals* during the actual *transport*.

5. Managers of facilities at the start and at the end of the *journey* and at *resting points* are responsible for:

a) providing suitable premises for *loading*, *unloading* and securely holding the *animals*, with water and feed when required, and with protection from adverse weather conditions until further transport, sale or other use (including rearing or slaughter);

b) providing an adequate number of *animal handlers* to load, unload, drive and hold *animals* in a manner that causes minimum stress and injury; in the absence of a separate *animal handler*, the driver is the *animal handler*;

c) minimising the opportunities for disease transmission;

d) providing appropriate facilities, with water and feed when required;

e) providing appropriate facilities for emergencies;

f) providing facilities for washing and disinfecting *vehicles* after *unloading*;

g) providing facilities and competent staff to allow the humane *killing* of *animals* when required;

h) ensuring proper rest times and minimal delay during stops.

6. The responsibilities of *Competent Authorities* include:

a) establishing minimum standards for *animal welfare*, including requirements for inspection of *animals* before, during and after their travel, defining 'fitness to travel' and appropriate certification and record keeping;

b) setting standards for facilities, *containers* and *vehicles* for the transport of *animals*;

c) setting standards for the competence of *animal handlers*, drivers and managers of facilities in relevant issues in *animal welfare*;

d) ensuring appropriate awareness and training of *animal handlers*, drivers and managers of facilities in relevant issues in *animal welfare*;

e) implementation of the standards, including through accreditation of / interaction with other organisations;

f) monitoring and evaluating the effectiveness of standards of health and other aspects of *welfare*;

g) monitoring and evaluating the use of veterinary medications;

h) giving animal consignments priority at frontiers in order to allow them to pass without unnecessary delay.

7. All individuals, including *veterinarians*, involved in transporting *animals* and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.

8. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant *animal welfare* problems which occurred during the *journey*.

Article 7.3.4.

Competence

1. All people responsible for *animals* during *journeys*, should be competent according to their responsibilities listed in Article 7.3.3. Competence may be gained through formal training and/or practical experience.

2. The assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

a) planning a *journey*, including appropriate *space allowance*, and feed, water and ventilation requirements;

b) responsibilities for *animals* during the *journey*, including *loading* and *unloading*;

c) sources of advice and assistance;

d) animal behaviour, general signs of *disease*, and indicators of poor *animal welfare* such as stress, pain and fatigue, and their alleviation;

e) assessment of fitness to travel; if fitness to travel is in doubt, the *animal* should be examined by a *veterinarian*;

f) relevant authorities and applicable transport regulations, and associated documentation requirements;

g) general disease prevention procedures, including cleaning and *disinfection*;

h) appropriate methods of animal handling during transport and associated activities such as assembling, *loading* and *unloading*;

i) methods of inspecting *animals*, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including humane *killing*;

j) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and

k) maintaining a *journey* log and other records.

Annex XIII (contd)

Article 7.3.5.

Planning the journey

1. General considerations

   a) Adequate planning is a key factor affecting the *welfare* of *animals* during a *journey*.

   b) Before the *journey* starts, plans should be made in relation to:

      i) preparation of *animals* for the *journey*;

      ii) choice of road, rail, roll-on roll-off vessels or *containers*;

      iii) nature and duration of the *journey*;

      iv) *vehicle* design and maintenance, including roll-on roll-off vessels;

      v) required documentation;

      vi) *space allowance*;

      vii) rest, water and feed;

      viii) observation of *animals* en route;

      ix) control of *disease*;

      x) emergency response procedures;

      xi) forecast weather conditions (e.g. conditions being too hot or too cold to travel during certain periods of the day);

      xii) transfer time when changing mode of transport, and

      xiii) waiting time at frontiers and inspection points.

   c) Regulations concerning drivers (for example, maximum driving periods) should take into account *animal welfare* whenever possible.

2. Preparation of animals for the journey

   a) When *animals* are to be provided with a novel diet or method of water provision during transport, an adequate period of adaptation should be planned. For all *animals* it is essential that the rest stops during long journeys are long enough to fulfil each *animal*'s need for feed and water. Species-specific short period of feed deprivation prior to *loading* may be desirable

   b) *Animals* more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. *Animal handlers* should handle and load *animals* in a manner that reduces their fearfulness and improves their approachability.

   c) Behaviour-modifying compounds (such as tranquillisers) or other medication should not be used routinely during transport. Such compounds should only be administered when a problem exists in an individual *animal*, and should be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

3. Nature and duration of the journey

The maximum duration of a *journey* should be determined according to factors such as:

a) the ability of the *animals* to cope with the stress of transport (such as very young, old, lactating or pregnant *animals*);

b) the previous transport experience of the *animals*;

c) the likely onset of fatigue;

d) the need for special attention;

e) the need for feed and water;

f) the increased susceptibility to injury and *disease*;

g) *space allowance*, *vehicle* design, road conditions and driving quality;

h) weather conditions;

i) *vehicle* type used, terrain to be traversed, road surfaces and quality, skill and experience of the driver.

4. Vehicle and container design and maintenance

a) *Vehicles* and *containers* used for the transport of *animals* should be designed, constructed and fitted as appropriate for the species, size and weight of the *animals* to be transported. Special attention should be paid to avoid injury to *animals* through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers and *animal handlers* while carrying out their responsibilities should be emphasised.

b) *Vehicles* and *containers* should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for *animals* to escape.

c) In order to minimise the likelihood of the spread of infectious *disease* during transport, *vehicles* and *containers* should be designed to permit thorough cleaning and *disinfection*, and the containment of faeces and urine during a *journey*.

d) *Vehicles* and *containers* should be maintained in good mechanical and structural condition.

e) *Vehicles* and *containers* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system (natural or mechanical) should be effective when the *vehicle* is stationary, and the airflow should be adjustable.

f) *Vehicles* should be designed so that the faeces or urine from *animals* on upper levels do not soil *animals* on lower levels, nor their feed and water. This condition is not applicable for *poultry*. They are generally transported in plastic crates which are designed to let air flow through in all directions to obtain a better ventilation.

g) When *vehicles* are carried on board ferries, facilities for adequately securing them should be available.

h) If feeding or watering while the *vehicle* is moving is required, adequate facilities on the *vehicle* should be available.

i) When appropriate, suitable bedding should be added to *vehicle* floors to assist absorption of urine and faeces, to minimise slipping by *animals*, and protect *animals* (especially young *animals*) from hard flooring surfaces and adverse weather conditions.

5. Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers

a) *Vehicles* and *containers* should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the *vessel*.

b) *Vehicles* and *containers* should be secured to the *vessel* before the start of the sea *journey* to prevent them being displaced by the motion of the *vessel*.

c) Roll-on/roll-off *vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the *animals* are transported in a secondary *vehicle*/*container* on enclosed decks.

6. Space allowance

a) The number of *animals* which should be transported on a *vehicle* or in a *container* and their allocation to compartments should be determined before *loading*.

b) The space required on a *vehicle* or in a *container* depends upon whether or not the *animals* need to lie down (for example, cattle, sheep, pigs, camels and *poultry*), or to stand (horses). *Animals* which will need to lie down often stand when first loaded or when the *vehicle* is driven with too much lateral movement or sudden braking.

c) When *animals* lie down, they should all be able to adopt a normal lying posture, without being on top of one another, and allowing necessary thermoregulation.

d) When *animals* are standing, they should have sufficient space to adopt a balanced position as appropriate to the climate and species transported.

e) The amount of headroom necessary depends on the species of *animal*. Each *animal* should be able to assume its natural standing position for transport (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vehicle*, and there should be sufficient headroom to allow adequate airflow over the *animals*. These conditions will not normally apply to *poultry* except for one day old chicks. However, under tropical and subtropical conditions *poultry* benefit from having adequate head room to allow head cooling.

EU Comment

Because of its importance for animal welfare, the EU wishes to reiterate its previous comment. If it is not considered by the OIE the EU wishes to have a clear explanation on the OIE's scientific background on why the comment is not being taken in to account.

In point 6 e) of Art 7.3.5, in the first sentence of the paragraph above and after the term

"vehicle", the EU wishes to replace the rest of the sentence as follows:

"…vehicle. This condition should not apply to poultry except for one day old chicks.

There should always be sufficient headroom to allow adequate airflow over the animals".

Justification

1. Day old chicks should be able to stand in order to avoid to be trampled. Scientific evidence is provided in the EFSA Scientific Report on the welfare of animals during transport, March 2004.

2. Sufficient headroom is always necessary for an adequate airflow even outside subtropical or tropical conditions.

f) Calculations for the *space allowance* for each *animal* should be carried out using the figures given in a relevant national or international document. The number and size of pens on the *vehicle* should be varied to where possible accommodate already established groups of *animals* while avoiding group sizes which are too large.

g) Other factors which may influence space allowance include:

i) vehicle/container design;

ii) length of *journey*;

iii) need to provide feed and water on the *vehicle*;

iv) quality of roads;

v) expected weather conditions;

vi) category and sex of the *animals*.

h) Rest, water and feed

i) Suitable water and feed should be available as appropriate and needed for the species, age, and condition of the *animals*, as well as the duration of the *journey*, climatic conditions, etc.

ii) *Animals* should be allowed to rest at *resting points* at appropriate intervals during the *journey*. The type of transport, the age and species of the *animals* being transported, and climatic conditions should determine the frequency of rest stops and whether the *animals* should be unloaded. Water and feed should be available during rest stops.

7. Ability to observe animals during the journey

a) *Animals* should be positioned to enable each *animal* to be observed regularly during the *journey* to ensure their safety and good *welfare*. This condition will not normally apply to *poultry*

EU comment

In point 7.a) of Art 7.3.5, the following text should replace the proposed new text: "In the case of poultry this should be applied as far as possible".

Justification

The text might otherwise suggest that it is not necessary at all in regards to poultry.

b) If the *animals* are in crates or on multi-tiered *vehicles* which do not allow free access for observation, for example where the roof of the tier is too low, *animals* cannot be inspected adequately, and serious injury or *disease* could go undetected. In these circumstances, a shorter *journey* duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

8. Control of disease

As animal transport is often a significant factor in the spread of infectious *diseases*, *journey* planning should take the following into account:

a) mixing of *animals* from different sources in a single consignment should be minimised;

b) contact at *resting points* between *animals* from different sources should be avoided;

c) when possible, *animals* should be vaccinated against *diseases* to which they are likely to be exposed at their destination;

d) medications used prophylactically or therapeutically should be approved by the *Veterinary Authority* of the *exporting country* and the *importing country* and should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

9. Emergency response procedures

There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

10. Other considerations

a) Extreme weather conditions are hazardous for *animals* undergoing transport and require appropriate *vehicle* design to minimise risks. Special precautions should be taken for *animals* that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, *animals* should not be transported at all.

b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 7.3.6.

Documentation

1. *Animals* should not be loaded until the documentation required to that point is complete.

2. The documentation accompanying the consignment should include:

a) *journey* travel plan and emergency management plan;

b) date, time and place of *loading* and *unloading*;

c) veterinary certification, when required;

d) *animal welfare* competencies of the driver (under study);

e) *animal identification* to allow *animal traceability* to the premises of departure and, where possible, to the premises of origin;

f) details of any *animals* considered at particular risk of suffering poor *welfare* during transport (point 3e) of Article 7.3.7.);

g) documentation of the period of rest, and access to feed and water, prior to the *journey*;

h) *stocking density* estimate for each load in the consignment;

i) the *journey* log - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.

3. When veterinary certification is required to accompany consignments of *animals*, it should address:

a) fitness of *animals* to travel;

b) *animal identification* (description, number, etc.);

c) health status including any tests, treatments and vaccinations carried out;

d) when required, details of *disinfection* carried out.

At the time of certification, the *veterinarian* should notify the *animal handler* or the driver of any factors affecting the fitness of *animals* to travel for a particular *journey*.

Article 7.3.7.

Pre-journey period

1. General considerations

a) Pre-*journey* rest is necessary if the *welfare* of *animals* has become poor during the collection period because of the physical environment or the social behaviour of the *animals*. The need for rest should be judged by a *veterinarian* or other competent person.

b) Pre-*journey* assembly/holding areas should be designed to:

i) securely hold the *animals*;

ii) maintain a safe environment from hazards, including predators and *disease*;

iii) protect *animals* from exposure to severe weather conditions;

iv) allow for maintenance of social groups;

v) allow for rest, and appropriate water and feed.

c) Consideration should be given to the previous transport experience, training and conditioning of the *animals*, if known, as these may reduce fear and stress in *animals*.

d) Feed and water should be provided pre-journey if the *journey* duration is greater than the normal inter-feeding and drinking interval for the *animal*. Recommendations for specific-species are described in detail in Article 7.3.12.

e) When *animals* are to be provided with a novel diet or method of feed or water provision during the *journey*, an adequate period of adaptation should be allowed.

f) Before each *journey*, *vehicles* and *containers* should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress and risks to the *animals*.

g) Where an *animal handler* believes that there is a significant risk of *disease* among the *animals* to be loaded or significant doubt as to their fitness to travel, the *animals* should be examined by a *veterinarian*.

2. Selection of compatible groups

Compatible groups should be selected before transport to avoid adverse *animal welfare* consequences. The following recommendations should be applied when assembling groups of *animals*:

a) *Animals* reared together should be maintained as a group; *animals* with a strong social bond, such as a dam and offspring, should be transported together.

Annex XIII (contd)

b) *Animals* of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 7.3.12.). For some species, *animals* from different groups should not be mixed because poor *welfare* occurs unless they have established a social structure.

c) Young or small *animals* should be separated from older or larger *animals*, with the exception of nursing mothers with young at foot.

d) *Animals* with horns or antlers should not be mixed with *animals* lacking horns or antlers unless judged to be compatible.

e) *Animals* of different species should not be mixed unless they are judged to be compatible.

3. Fitness to travel

a) Each *animal* should be inspected by a *veterinarian* or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, the *animal* should be examined by a *veterinarian*. *Animals* found unfit to travel should not be loaded onto a *vehicle*, except for transport to receive veterinary attention.

b) Humane and effective arrangements should be made by the owner and the agent for the handling and care of any *animal* rejected as unfit to travel.

c) *Animals* that are unfit to travel include, but may not be limited to:

i) those that are sick, injured, weak, disabled or fatigued;

ii) those that are unable to stand unaided and bear weight on each leg;

iii) those that are blind in both eyes;

iv) those that cannot be moved without causing them additional suffering;

v) newborn with an unhealed navel;

vi) pregnant *animals* which would be in the final 10% of their gestation period at the planned time of *unloading*;

vii) females travelling without young which have given birth within the previous 48 hours;

viii) those whose body condition would result in poor *welfare* because of the expected climatic conditions.

d) Risks during transport can be reduced by selecting *animals* best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

e) *Animals* at particular risk of suffering poor *welfare* during transport and which require special conditions (such as in the design of facilities and *vehicles*, and the length of the *journey*) and additional attention during transport, may include:

i) large or obese individuals;

ii) very young or old *animals*;

iii) excitable or aggressive *animals*;

iv) *animals* which have had little contact with humans;

v) *animals* subject to motion sickness;

vi) females in late pregnancy or heavy lactation, dam and offspring;

vii) *animals* with a history of exposure to stressors or pathogenic agents prior to transport;

viii) *animals* with unhealed wounds from recent surgical procedures such as dehorning.

4. Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 7.3.12.

Article 7.3.8.

Loading

1. Competent supervision

a) *Loading* should be carefully planned as it has the potential to be the cause of poor *welfare* in transported *animals*.

b) *Loading* should be supervised and/or conducted by *animal handlers*. The *animals* are to be loaded quietly and without unnecessary noise, harassment or force. Untrained assistants or spectators should not impede the process.

c) When *containers* are loaded onto a *vehicle*, this should be carried out in such a way to avoid poor *annimal welfare*.

2. Facilities

a) The facilities for *loading* including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the *animals* with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.

b) *Loading* facilities should be properly illuminated to allow the *animals* to be observed by *animal handler(s)*, and to allow the ease of movement of the *animals* at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside *vehicles/containers*, in order to minimise baulking. Dim light levels may be advantageous for the catching of *poultry* and some other *animals*. Artificial lighting may be required. Loading ramps and other facilities should have a non-slippery flooring.

c) Ventilation during *loading* and the *journey* should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each *animal*. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for *animals*.

Annex XIII (contd)

3. Goads and other aids

When moving *animals*, their species-specific behaviour should be used (see Article 7.3.12.). If goads and other aids are necessary, the following principles should apply:

a) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.

b) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

c) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.

d) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.

e) Excessive shouting at *animals* or making loud noises (e.g., through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.

f) The use of well trained dogs to help with the *loading* of some species may be acceptable.

g) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.

h) Conscious *animals* should not be thrown, dragged or dropped.

i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling as a result of their usage.

Article 7.3.9.

Travel

1. General considerations

a) Drivers and animal handlers should check the load immediately before departure to ensure that the *animals* have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip, especially at rest or refuelling stops or during meal breaks when the *vehicle* is stationary.

b) Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the *animals*.

2. Methods of restraining or containing animals

a) Methods of restraining *animals* should be appropriate to the species and age of *animals* involved and the training of the individual *animal*.

b) Recommendations for specific species are described in detail in Article 7.3.12.

3. Regulating the environment within vehicles or containers

a) *Animals* should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the environment within *vehicles* or *containers* will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented.

b) The environment within *vehicles* or *containers* in hot and warm weather can be regulated by the flow of air produced by the movement of the *vehicle*. In warm and hot weather, the duration of *journey* stops should be minimised and *vehicles* should be parked under shade, with adequate and appropriate ventilation.

c) To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.

4. Sick, injured or dead animals

a) A driver or an *animal handler* finding sick, injured or dead *animals* should act according to a predetermined emergency response plan.

b) Sick or injured *animals* should be segregated.

c) Ferries (roll-on roll-off) should have procedures to treat sick or injured *animals* during the *journey*.

d) In order to reduce the likelihood that animal transport will increase the spread of infectious *disease*, contact between transported *animals*, or the waste products of the transported *animals*, and other farm *animals* should be minimised.

e) During the *journey*, when disposal of a dead *animal* becomes necessary, this should be carried out in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.

f) When *killing* is necessary, it should be carried out as quickly as possible and assistance should be sought from a *veterinarian* or other person(s) competent in humane *killing* procedures. Recommendations for specific species are described in Chapter 7.6. on killing of *animals* for disease control purposes.

5. Sick, injured or dead animals

a) If *journey* duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the *animals* (appropriate for their species and age) carried in the *vehicle* should be provided. There should be adequate space for all *animals* to move to the feed and water sources and due account taken of likely competition for feed.

b) Recommendations for specific species are described in detail in Article 7.3.12.

Annex XIII (contd)

6. Rest periods and conditions

a) *Animals* that are being transported should be rested at appropriate intervals during the *journey* and offered feed and water, either on the *vehicle* or, if necessary, unloaded into suitable facilities.

b) Suitable facilities should be used en route, when resting requires the *unloading* of the *animals*. These facilities should meet the needs of the particular animal species and should allow access of all *animals* to feed and water.

7. In-transit observations

a) *Animals* being transported by road should be observed soon after a *journey* is commenced and whenever the driver has a rest stop. After meal breaks and refuelling stops, the *animals* should be observed immediately prior to departure.

b) *Animals* being transported by rail should be observed at each scheduled stop. The responsible rail transporter should monitor the progress of trains carrying *animals* and take all appropriate action to minimise delays.

c) During stops, it should be ensured that the *animals* continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 7.3.10.

Unloading and post-journey handling

1. General considerations

a) The required facilities and the principles of animal handling detailed in Article 7.3.8. apply equally to *unloading*, but consideration should be given to the likelihood that the *animals* will be fatigued.

b) *Unloading* should be supervised and/or conducted by an *animal handler* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. *Animals* should be unloaded from the *vehicle* into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for *unloading* to proceed quietly and without unnecessary noise, harassment or force.

c) Facilities should provide all *animals* with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.

d) For details regarding the *unloading* of *animals* at a *slaughterhouse*, see Chapter 7.5. on slaughter of animals for human consumption.

2. Sick or injured animals

a) An *animal* that has become sick, injured or disabled during a *journey* should be appropriately treated or humanely killed (see Chapter 7.6. on killing of *animals* for disease control purposes). If necessary, veterinary advice should be sought in the care and treatment of these *animals*. In some cases, where *animals* are non-ambulatory due to fatigue, injury or sickness, it may be in the best *welfare* interests of the *animal* to be treated or killed aboard the *vehicle*. Assistance should be sought from a *veterinarian* or other person(s) competent in humane *killing* procedures.

b) At the destination, the *animal handler* or the driver during transit should ensure that responsibility for the *welfare* of sick, injured or disabled *animals* is transferred to a *veterinarian* or other suitable person.

c) If treatment or humane *killing* is not possible aboard the *vehicle*, there should be appropriate facilities and equipment for the humane *unloading* of *animals* that are non-ambulatory due to fatigue, injury or sickness. These *animals* should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities should be available for sick or injured *animals*.

d) Feed, if appropriate, and water should be available for each sick or injured *animal*.

3. Addressing disease risks

The following should be taken into account in addressing the greater risk of *disease* due to animal transport and the possible need for segregation of transported *animals* at the destination:

a) increased contact among *animals*, including those from different sources and with different disease histories;

b) increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression;

c) exposure of *animals* to pathogens which may contaminate *vehicles*, *resting points*, *markets*, etc.

4. Cleaning and disinfection

a) *Vehicles*, crates, *containers*, etc. used to carry the *animals* should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing with water and detergent. This should be followed by *disinfection* when there are concerns about disease transmission.

b) Manure, litter, bedding and the bodies of any *animals* which die during the *journey* should be disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.

c) Establishments like livestock *markets*, *slaughterhouses*, resting sites, railway stations, etc. where *animals* are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of *vehicles*.

Article 7.3.11.

Actions in the event of a refusal to allow the completion of the journey

1. The *welfare* of the *animals* should be the first consideration in the event of a refusal to allow the completion of the *journey*.

2. When the *animals* have been refused import, the *Competent Authority* of the *importing country* should make available suitable isolation facilities to allow the *unloading* of *animals* from a *vehicle* and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:

a) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;

b) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to a *veterinarian*, where possible an OIE *veterinarian(s)* appointed by the Director General, to assess the health status of the *animals* with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing;

c) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the health and other aspects of the *welfare* of the *animals*;

d) if the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

3. In the event that a *Competent Authority* requires the *animals* to remain on the *vehicle*, the priorities should be:

a) to allow provisioning of the *vehicle* with water and feed as necessary;

b) to provide urgently in writing the reasons for the refusal;

c) to provide urgent access to an independent *veterinarian(s)* to assess the health status of the *animals*, and the necessary facilities and approvals to expedite the required diagnostic testing in the event of a refusal for animal health reasons;

d) to provide access to allow continued assessment of the health and other aspects of the *welfare* of the *animals*, and the necessary actions to deal with any animal issues which arise.

4. The OIE should utilise its informal procedure for dispute mediation to identify a mutually agreed solution which will address animal health and any other *welfare* issues in a timely manner.

Article 7.3.12.

Species-specific issues

Camelids of the new world in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single *animal* will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the *animals* rise.

Cattle are sociable *animals* and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the *animals* try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross *animals* are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid "dead end" in passages.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to *animals* should be avoided. Bullying is particularly serious in goats and can reflect demands for personal space. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Horses in this context include donkeys, mules and hinnies. They have good eyesight and a very wide angle of vision. They may have a history of *loading* resulting in good or bad experiences. Good training should result in easier *loading*, but some horses can prove difficult, especially if they are inexperienced or have associated *loading* with poor transport conditions. In these circumstances, two experienced *animal handlers* can load an *animal* by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed. Horses are prone to respiratory *disease* if they are restricted by period by tethers that prevent the lowering and lifting of their heads.

Pigs have poor eyesight, and may move reluctantly in unfamiliar surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good 'rule-of-thumb' is that no step should be higher than the pig's front knee. Serious aggression may result if unfamiliar *animals* are mixed. Pigs are highly susceptible to heat stress. Pigs are susceptible to motion sickness when in transit. Feed deprivation prior to loading may be beneficial to prevent motion sickness.

Sheep are sociable *animals* with good eyesight, a relatively subtle and undemonstrative behaviour and a tendency to "flock together", especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Crowding of sheep may lead to damaging aggressive and submissive behaviours as *animals* try to maintain personal space. Sheep may become agitated if they are singled out for attention, or kept alone, and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

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CHAPTER 7.4.

TRANSPORT OF ANIMALS BY AIR

EU comment

The EU has one comment on article 7.47.1.

Article 7.4.1.

Livestock containers

1. Design

a) General principles of design

The *container* should:

- conform to the size of the standard pallet of the aircraft that will be used to transport *animals*; ~~the common sizes are: 224 x 318 cm (88 x 125 in.) and 244 x 318 cm (96 x 125 in.);~~

EU comment

In the first bullet point of point 1.a) of Art 7.4.1, the EU wishes the figures to be maintained.

Justification

It is not clear why the figures are taken out. Unless there is a clear rationale for this, they should be kept.

- not be constructed of material that could be harmful to the *animals* health or *welfare*;
- allow observation of the *animals* and be marked on opposite sides with the International Air Transport Association (IATA) symbols which indicate *animals* and the upright position;
- allow emergency access to *animals*;
- allow the *animal* to stand in its normal position without touching the roof of the *container* or, in the case of open *containers*, the restraining nets, and provide at least 10 cm (4 in.) clearance above the *animal*'s head when standing in its normal position; in the case of horses, provide sufficient space above the horses head (21 cm, 8 in. recommended) to allow for the movement required to maintain the horses balance;
- protect the *animals* from adverse weather;
- ensure *animals* stand on a suitable floor to prevent slipping or injury;
- have adequate strength to ensure the safety of the *animals* and to prevent the *animals* from escaping;
- ensure doors can be opened and closed easily, but be secured so that they cannot be opened accidentally;
- be free of any nails, bolts and other protrusions or sharp edges that could cause injuries;

- be designed to minimise the risk of any opening or space entrapping any portion of the *animals* body;
- if reusable, crates should be constructed of impermeable material that is easily cleaned and disinfected;
- ensure faeces and urine cannot escape from the crate; this requires a minimum upturn of 20 cm but it should not block any ventilation openings;
- if designated for stacking be stable, not block any ventilation space and prevent urine and faeces from leaking into the containers below when stacked;
- allow for a facility for provision of water and possibly food during transportation of longer than 6 hours duration.

b) Ventilation

The *container* design should:

- provide adequate ventilation taking into consideration the species *stocking densities*, maximum temperature and humidity of the points of departure, destination, and any interim technical stops;
- allow the normal resting or sleeping position to be assumed for certain species and juvenile *animals*;
- ensure there is no dead air space in the *container*;
- provide ventilation openings on the walls equal to at least 16% of the wall area; this may be reduced if the *container* has an open top;
- in the case of two-tiered *containers*, ventilation in the sides should be for cattle equivalent to not less than 20% of the floor area of each deck, and for pigs and sheep up to 40% of the floor area of each deck;
- have ventilation openings on all four sides of the crate except that two walls may have reduced ventilation space and the other walls have increased space where required by the positioning of the crates during transportation and/or the ventilation pattern of the aircraft;
- ensure that any internal supports or dividers do not block the cross ventilation;
- not have a solid wall above the height of the *animal*'s head in normal resting position;
- in those species where the mouth is normally held near the floor, have at least 25 cm (10 in.) of ventilation space at the level of the *animal*'s head; this opening should be divided in two with a maximum height for any opening of 13 cm; in all *containers*, there should be a sufficiently large ventilation opening at a height of 25 cm to 30 cm (10 to 11 in.) above floor level on all four sides to allow for circulation;
- have some physical means of ensuring the ventilation space is not blocked, such as the use of cleats (wedges) or allowing space between the outside of the *container* and the pallet.

2. Species requirements

In general, fractious *animals* or *animals* in late pregnancy should not be transported by air (see Article 7.4.2.).

a) Horses

Should be transported in *containers* and be separated from each other if they are more than 145 cm (57 in.) in height.

Crates used to transport horses should:

- be strong enough to prevent unruly horses from breaking or escaping from the *container* under any circumstances;
- in the case of multi-horse *containers*, have partitions of sufficient strength and size to separate the horses and to support each horse's weight;
- adjust to allow mare and foal to travel together;
- provide the same percentage of open space for ventilation as required in point 1 above, divided between the two side walls; however, if the access doors are constructed in such a manner that they may be left open during the flight, the door space may be included in the ventilation space;
- be constructed to minimise noise;
- allow access to the head during the flight;
- have the front end notched and padded to accept the neck of the *animal*;
- have a secure point for attaching restraining devices;
- have a front and rear barrier that will restrict the movement of the horse and will ensure that liquids are deflected into the *container*;
- ensure horses cannot bite other *animals*;
- be constructed to resist kicking;
- have no fittings or projections in the area likely to be kicked, metal plates should be covered with a protective material;
- ramps shall be non-skid in nature, have foot battens, and be of a maximum slope of 25 degrees when the *container* is on a standard 50 cm (20 in.) dolly;
- not have a step up or down of more than 25 cm (10 in.).

b) Swine

- Crate design and shipment planning should recognize that swine are extremely susceptible to high heat and humidity and that they normally carry their head near the floor.
- In the use of multi-tiered crates, special attention should be paid to ensure air can move through the crate, in accordance with the aircraft's ventilation pattern and capacity to remove heat.
- Crate construction should take into consideration the tendency for mature swine to chew.
- Litter should be dust-free, shavings or other non toxic materials may be used but not sawdust.
- *Containers* for immature swine should only be constructed when flight is imminent, since rapid growth can result in undersized containers if the flight is delayed.
- In order to reduce fighting, swine shipped in group pens should be housed together as a group prior to shipment and not be mixed with other swine before loading on the aircraft.

- Mature boars and incompatible females should be shipped in individual crates.
- Individual crates should be 20 cm (8 in.) longer than the body, 15 cm (6 in.) higher than the loin of the pig and of sufficient width, to allow the pigs to lie on their side.

c) Cattle

Crates used to transport cattle should:

- if multi-tiered or roofed, have at least 33% of the roof and four walls as open space;
- have at least one ventilation opening 20-25 cm (8-10 in.) above the floor which is of such width that it will not cause injuries to the feet.

Adult bulls should be transported separately unless they have been accustomed to each other. Cattle with and without horns should be separated from each other.

d) Poultry

The most current *container* requirement published by IATA should be adhered to.

Crates/*containers* containing *poultry* should be handled and carried carefully with no unnecessary tilting.

The majority of birds transported by air will be newly hatched chicks. These *animals* are very vulnerable to sudden changes in temperature.

e) Other species

- *Animals* that normally exhibit a herding instinct, including buffalo and deer, can be shipped in group *containers* providing the mental and physical characteristics of the species are taken into consideration.
- All crates used to move such *animals* should have a roof or other method of preventing the *animals* from escaping.
- *Animals* in which the horns or antler cannot be removed, should be transported individually.
- Deer should not be transported in velvet nor in rut.

Article 7.4.2.

Recommendations for pregnant animals

Heavily pregnant *animals* should not be carried except under exceptional circumstances. Pregnant *animals* should not be accepted when the last service or exposure to a male prior to departure has exceeded the following time given here for guidance only:

Females	**Maximum number of days since the last service**
Horses	300
Cows	250
Deer (axis, fallow and sika)	170
(red deer, reindeer)	185
Ewes (sheep)	115
Nannies (goats)	115
Sows (pigs)	90

Where service dates or date of last exposure to a male are not available, the *animals* should be examined by a *veterinarian* to ensure that pregnancy is not so advanced that *animals* are likely to give birth during transport or suffer unnecessarily.

Any *animal* showing udder engorgement and slackening of the pelvic ligament should be refused.

Article 7.4.3.

Stocking density

The current *stocking densities* agreed by the International Air Transport Association (IATA) should continue to be accepted. However, the graphs giving the space requirements should be extended to take into account *animals* larger and smaller than those dealt with currently.

1. General considerations

When calculating stocking rates, the following should be taken into account:

a) it is essential that accurate weights of *animals* are obtained in view of the limitations imposed by the load capabilities of the aircraft and the space required per *animal*;

b) in narrow bodied aircraft, there is a loss of floor area in the upper tier of two-tier penning due to the contours of the aircraft;

c) space available should be calculated on the inside measurements of the crates or penning system used, not on the floor space of the aircraft;

d) multi-tiered crates, high outdoor temperatures at departure, arrival or stopover points, or extreme length of the trip will require an increase in the amount of space per *animal*; a 10% decrease in *stocking density* is recommended for trips in excess of 24 hours;

e) special attention should be paid to the transport of sheep in heavy wool which require an increase in space allotted per *animal* and to pigs which have limited ability to dissipate heat;

f) *animals* confined in groups, especially in pens, should be stocked at a high enough density to prevent injuries at take-off, during turbulence and at landing, but not to the extent that individual *animals* cannot lie down and rise without risk of injury or crushing;

g) in multi-tiered shipments, it should be recognized that the ventilation and cooling capacity of the aircraft is the limiting factor, especially in narrow bodied aircraft. Ventilation capacity varies on each individual aircraft and between aircraft of the same model.

2. Recommendations for stocking densities

The following table gives *stocking density* recommendations for different domestic species. The values are expressed in kilograms and metres.

Annex XIII (contd)

Species	Weight	Density	Space/ animal	No. of animals per	Animals per single tier pallet		
	kg	kg/m²	m²	10 m²	214x264 cm	214x308 cm	234x308 cm
Calves	50 70 80 90	220 246 266 280	0.23 0.28 0.30 0.32	43 35/6 33 31	24 20 18 17	28 23 21 20	31 25 24 22
Cattle	300 500 600 700	344 393 408 400	0.84 1.27 1.45 1.63	11-12 8 6-7 6	6 4 3-4 3	7 5 4 3-4	8 5 4-5 4
Sheep	25 70	147 196	0.17 0.36	59 27/8	32 15	37 18	42 20
Pigs	25 100	172 196	0.15 0.51	67 20	37 10	44 12	48 14

Article 7.4.4.

Preparation for air transport of livestock

1. Health and customs requirements

   The legal requirements including animal health, *welfare* and species conservation, should be ascertained from the country of destination and any in *transit countries* before the *animals* are assembled or the transportation is arranged.

   Contact the *Veterinary Authorities* in the country of origin regarding veterinary certification.

   Planning of the transportation should take into account weekends, holidays and airport closures.

   Verify that any proposed intransit stops or alternates will not jeopardise the importing or in *transit countries* health requirements.

   Waiting time at customs (cargo handling and clearance) should be reduced as much as possible to avoid *welfare* problems.

2. Environment

   Animals are affected by extremes of temperature. This is especially true of high temperature when compounded by high humidity. Temperature and humidity should therefore be taken into consideration when planning the shipment.

   Times of arrival, departure and stopovers should be planned so that the aircraft lands during the coolest hours.

   At outside temperatures of below 25°C at the landing point, the aircraft doors should be opened to ensure adequate ventilation. Confirmation should be received from government authorities that animal health legislation does not prevent opening of aircraft doors.

   When outside temperatures at any landing point exceed 25°C, prior arrangements should be made to have an adequate air-conditioning unit available when the plane lands.

3. Facilities and equipment

Specific arrangements should be made to ensure that holding and *loading* facilities including ramps, trucks, and air-conditioning units are available at departure, all in transit and arrival airports. This should include identification of specific staff who are responsible and the method of contacting them, e.g. telephone number and address.

Specific notification should be given to all those responsible for providing facilities or equipment at the destination and in transit stops immediately before departure.

Containers should be loaded so as to ensure access can be made to the *animals* at all times.

4. Preparation of animals

Vaccination should be done far enough in advance of the departure date to allow for immunity to develop.

Veterinary certification and serological testing should be arranged several weeks in advance of livestock shipment.

Many *animals* require acclimatisation before they are transported. *Animals* such as swine and wild herbivores should be separated and held in the groups that will occupy *containers*. Mixing of such *animals* immediately before or during transport is extremely stressing and should be avoided.

Incompatible *animals* should be transported singly.

Article 7.4.5.

Disinfection and disinfestation

1. Disinfection

a) Those parts of the interior of the aircraft destined for the carriage of *animals* should be thoroughly cleaned of all foreign matters using methods acceptable to aircraft management before being loaded.

b) These parts should be sprayed with a disinfectant:

i) suitable for the *diseases* which could be carried by the *animals*;

ii) that does not cause problems with the aircraft;

iii) that will not leave a residue hazardous to the *animals* being transported.

If in doubt, the airline should be consulted on the suitability of the disinfectant. A mechanical nebuliser should be used to minimise the amount of disinfectant used.

Suggested disinfectants currently in use are:

iv) 4% sodium carbonate and 0.1% sodium silicate;

v) 0.2% citric acid.

c) All removeable equipment, penning and *containers* including loading ramps should be thoroughly cleaned and disinfected in accordance with the requirements of both the *exporting* and *importing countries*.

Annex XIII (contd)

d) After *disinfection*, all equipment to be replaced in the aircraft should be washed with clean water to remove any traces of disinfectant to avoid any damage to the aircraft structures.

2. Disinfestation

Where *disinfestation* is required, the country requesting the action should be consulted for appropriate procedures.

The World Health Organisation (WHO) Recommendations on the Disinsectisation of Aircraft (*WHO Weekly Epidem. Rec.*, No. 7, 1985) are recognised as standard.

Article 7.4.6.

Radiation

Radioactive materials should be separated from live *animals* by a distance of at least 0.5 metre for journeys not exceeding 24 hours, and by a distance of at least 1.0 metre for journeys longer than 24 hours (reference: Technical instructions on storage and loading-separation of the International Civil Aviation Organisation). Special care should be taken with regard to pregnant *animals*, semen and embryos/ova.

Article 7.4.7.

Tranquilization

Experience has shown that there is considerable risk in sedating *animals* transported by air. Tranquilizers reduce the ability of the *animals* to respond to stress during transportation. In addition, the reaction of various species to tranquilization cannot always be foreseen. For these reasons, routine tranquilization is not recommended. Tranquilizers should only be used when a specific problem exists, and should be administered by a *veterinarian* or by a person who has been instructed in their use. Persons using these drugs should understand the full implications of the effects of the drug in air transport, e.g. certain *animals* such as horses and elephants should not go down in *containers*. Drugs should only be administered during the flight with the knowledge and consent of the captain.

In all cases, when tranquilizers are used, a note should be attached to the *container* stating the weight of the individual *animal*, the generic name of the drug used, the dose, the method and time of administration.

Article 7.4.8.

Destruction of carcasses

In the event of any animal *death* on board, the competent authority of the airport of destination should be notified in advance of landing.

Carcasses should be disposed of under the supervision of and to the satisfaction of the *Veterinary Authority* of the country the aircraft is in.

The method of disposal should be based on the risk of introducing a controlled *disease*.

For carcasses which represent a high risk of introducing *disease*, the following is recommended:

1. destruction by incineration, rendering or deep burial under the supervision of the *Veterinary Authority*;

2. if removed from the airport site, transportation in a closed, leakproof *container*.

Article 7.4.9.

Emergency slaughter

EU comment

The title of Art 7.4.9 should be replaced by "*Emergency killing*".

Justification

In this context, animals would not be slaughtered for human consumption; the term killing is therefore more appropriate.

Emergency *slaughter* of *animals* in aircraft should, in general, only occur when the safety of the aircraft, crew or other *animals* are involved.

Every aircraft transporting *animals* should have a method of killing the *animals* with minimum pain and someone trained in that method.

In all cases when horses or other large *animals* are to be carried, the method of killing should be discussed with the airline during the planning stages. Suitable methods are:

1. Captive bolt stunner, followed by an injection of a lethal chemical
    a) Operator should be trained to use the captive bolt stunner on the species or type of *animal* being transported.
    b) An expert should determine that the type of captive bolt pistol is adequate for all the *animals* being transported.

EU comment

In the above point 1. b) of Art 7.4.9, after the words "*captive bolt pistol*", the following text should be added "*and cartridge power*".

Justification

The power of the cartridge charge contained in the bolt is also important for a humane kill.

    c) Some airlines and countries may prohibit the carriage of captive bolt pistols.
    d) The user should recognise that the noise associated with the captive bolt may excite other *animals*.
    e) The requirement that the captive bolt pistol is accurately centered may be difficult to achieve with an excited *animal*.

EU comment

In the above point 1. e) of Art 7.4.9, the word "*centered*" should be replaced by "*positioned*".

Justification

The ideal position will vary with different animals and it may not be central in all cases

2. Injection of a chemical

   a) Various chemicals may be used to sedate, immobilize or kill *animals*.

   b) Central nervous system depressants such as barbiturate euthanasia solutions should be injected directly into a vein to be effective. This is not normally practical for anyone but an experienced *veterinarian* or an especially trained and experienced attendant, where the *animal* is sufficiently fractious to require euthanasia.

   c) Sedatives such as promazine and its derivatives may make the *animal* more fractious (see Article 7.4.7.).

   d) Immobilizing solutions such as succinylcholine are not humane.

3. Firearms

   Airlines do not permit the use of firearms which discharge a free bullet because of the danger to the aircraft.

Article 7.4.10.

Handling of food and waste material

Waste material which contains anything of animal origin including food, litter, manure, or animal feed should be handled, collected and disposed of in a manner that ensures it will not be fed to livestock. It should be collected in specified areas, and stored and transported in closed, leakproof *containers*.

Some *importing countries* legislation may prohibit or restrict the use of hay or straw during the transportation period. Unloading of hay, straw, other animal feed and litter may be restricted or prohibited by in *transit countries*.

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Article 7.4.11.

Disposal of food and waste material

Recommended methods of disposal are:

1. incineration to an ash;
2. heating at an internal temperature of at least of 100°C for 30 minutes, then disposal in a land fill site;
3. controlled burial in a land fill site.

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— text deleted

CHAPTER 7.5.

SLAUGHTER OF ANIMALS

EU comments

The EU acknowledges the work carried out by OIE to improve the chapter.

The EU would like the OIE to take into account, for future work, some specific comments that are reiterated within the text.

Article 7.5.1.

General principles

1. Object

These recommendations address the need to ensure the *welfare* of food *animals* during pre-slaughter and *slaughter* processes, until they are dead.

These recommendations apply to the *slaughter* in *slaughterhouses* of the following domestic *animals*: cattle, buffalo, bison, sheep, goats, camelids, deer, horses, pigs, ratites, rabbits and *poultry*. Other *animals*, wherever they have been reared, and all *animals* slaughtered outside *slaughterhouses* should be managed to ensure that their *transport*, *lairage*, *restraint* and *slaughter* is carried out without causing undue stress to the *animals*; the principles underpinning these recommendations apply also to these *animals*.

2. Personnel

Persons engaged in the *unloading*, moving, *lairage*, care, *restraint*, *stunning*, *slaughter* and bleeding of *animals* play an important role in the *welfare* of those *animals*. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the recommendations outlined in the present chapter and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the *slaughterhouse* and the *Veterinary Services* should ensure that *slaughterhouse* staff are competent and carry out their tasks in accordance with the principles of *animal welfare*.

3. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic *animals* should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in groups and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed at *slaughterhouses*.

The desire of some *animals* to control their personal space should be taken into account in designing facilities.

Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans i.e. tame have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

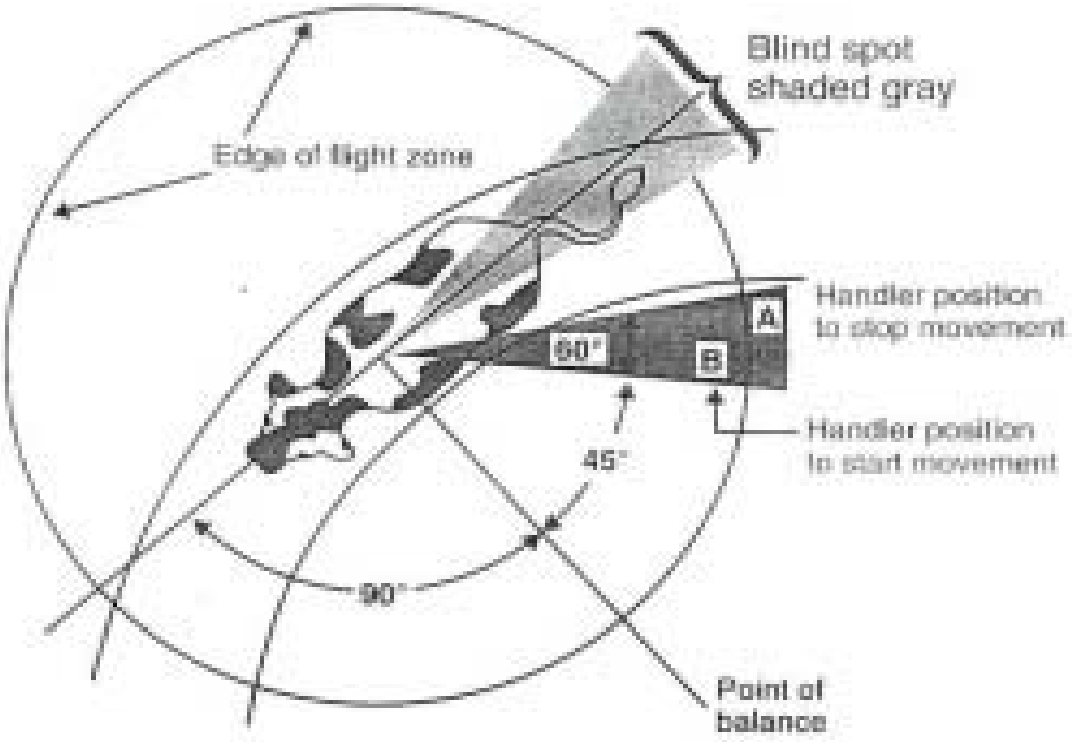
Animal handlers should use the point of balance at the *animal*'s shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

Domestic *animals* have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

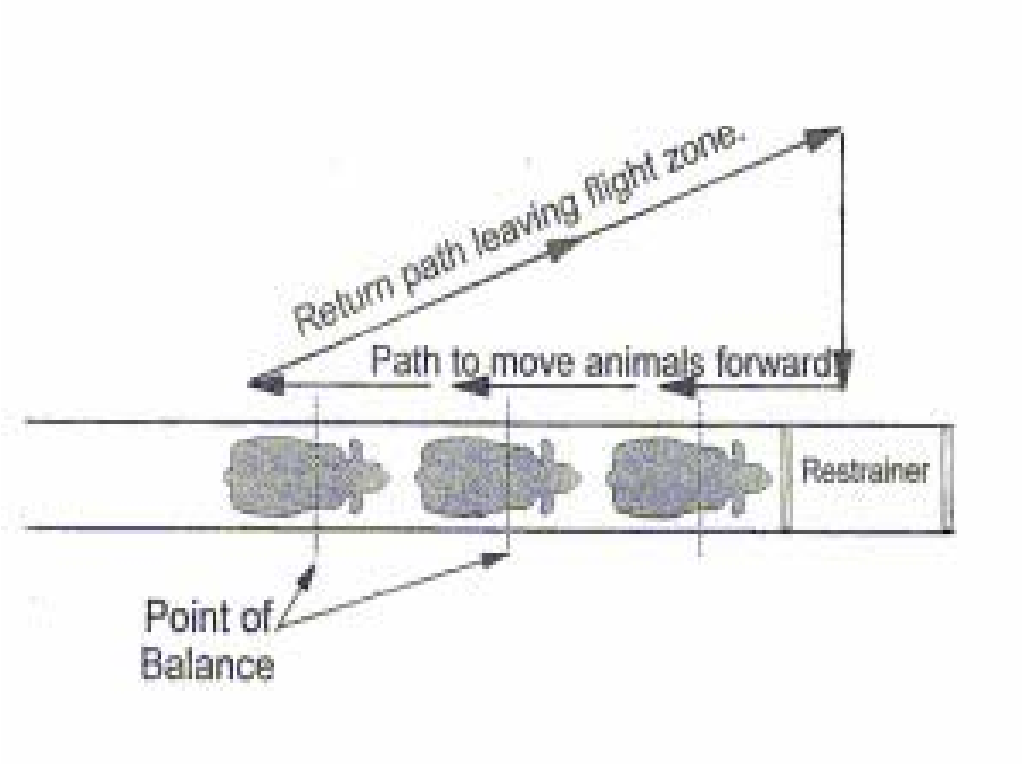
Although most domestic *animals* have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing *animals*.

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



4. Distractions and their removal

Distractions that may cause approaching *animals* to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors — move a lamp or change lighting;

b) dark entrances to chutes, races, stun boxes or conveyor restrainers — illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals*;

EU comment

The EU would like to reiterate its previous comment.

Under 7.5.1 (4) (b) the following words should be added after animals: "*or exposed them to sharp contrasts of light and dark,*"

c) *animals* seeing moving people or equipment up ahead — install solid sides on chutes and races or install shields;

d) dead ends — avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences — remove them;

f) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers — avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;

g) sounds of air hissing from pneumatic equipment — install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

h) clanging and banging of metal objects — install rubber stops on gates and other devices to reduce metal to metal contact;

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i) air currents from fans or air curtains blowing into the face of *animals* — redirect or reposition equipment.

Article 7.5.2.

Moving and handling animals

1. General considerations

Each slaughterhouse should have a dedicated plan for animal welfare. The purpose of such plan should be to maintain good level of animal welfare at all stages of the handling of animals until they are killed. The plan should contain standard operating procedures for each step of animal handling as to ensure that animal welfare is properly implemented based on relevant indicators. It also should include specific corrective actions in case of specific risks, like power failures or other circumstances that could negatively affect the welfare of animals.

Animals should be transported to *slaughter* in a way that minimises adverse animal health and *welfare* outcomes, and the transport should be conducted in accordance with the OIE recommendations for the transportation of *animals* (Chapters 7.2. and 7.3.).

The following principles should apply to *unloading animals*, moving them into *lairage* pens, out of the *lairage* pens and up to the *slaughter* point:

a) The conditions of the *animals* should be assessed upon their arrival for any *animal welfare* and health problems.

b) Injured or sick *animals*, requiring immediate *slaughter*, should be killed humanely and without delay, in accordance with the recommendations of the OIE.

EU Comment

The EU would like to reiterate its previous comment.

We suggest adding to paragraph 1b) of Article 7.5.2 the following sentence:

"Animals that are unable to walk should not be dragged to the place of slaughter but should be killed where they lie."

c) *Animals* should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of *animals* slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 99% of *animals* without their falling.

d) *Animals* for *slaughter* should not be forced to walk over the top of other *animals*.

e) *Animals* should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handlers* resort to violent acts to move *animals*, such as crushing or breaking tails of *animals*, grasping their eyes or pulling them by the ears. *Animal handlers* should never apply an injurious object or irritant substance to *animals* and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of *animals*, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small *animals* is permissible.

f) When using goads and other aids, the following principles should apply:

i) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme

cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.

ii) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

iii) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.

iv) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.

EU Comment

In the above point 1.f) iv) of Art 7.5.2, the word "*kicking*" should be added after the word "*whipping*".

Justification

This word was present in an earlier version and should not have been deleted as animals should not be kicked.

v) Excessive shouting at *animals* or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.

vi) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting such *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.

vii) Conscious *animals* should not be thrown, dragged or dropped.

~~viii) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling at a point in the slaughterhouse. Any risk of compromising animal welfare, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem. In addition to resource-based measures, outcome-based measures (e.g. bruises, lesions, behaviour, and mortality) should be used to monitor the level of welfare of the animals~~.

g) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling at a point in the *slaughterhouse*. Any risk of compromising *animal welfare*, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem. In addition to resource-based measures, outcome-based measures (e.g. bruises, lesions, behaviour, and mortality) should be used to monitor the level of *welfare* of the *animals*.

2. Specific considerations for poultry

Stocking density in transport crates should be optimum to suit climatic conditions and to maintain species-specific thermal comfort within *containers*.

Care is especially necessary during *loading* and *unloading* to avoid ~~wings or legs~~ body parts being caught on crates, leading to dislocated or broken ~~wing~~ bones in conscious birds. Such injuries will adversely affect *animal welfare*, carcass and *meat* quality.

Modular systems that involve tipping of live birds are not conducive to maintaining good *animal welfare*. These systems, when used, should be incorporated with a mechanism to facilitate birds sliding out of the transport system, rather than being dropped or dumped on top of each other from heights of more than a metre.

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed and/or constructed transport systems. Under this situation, operators *unloading* birds should ensure gentle release of trapped birds.

EU Comment

The EU would like to reiterate its previous comment.

In the above paragraph of Point 2) of Art 7.5.2, the following sentence should be added after "released of trapped birds":

"Appropriate maintenance of the crates should be in place."

Justification

Broken crate floors are the main cause of injured claws ~~caught in broken holes.~~

Drawers in modular systems and crates should be stacked and de-stacked carefully so as to avoid injury to birds.

Birds should have sufficient space so that all can lie down at the same time without being on top of each other.

Birds with broken bones and/or dislocated joints should be humanely killed before being hung on shackles for processing.

The number of *poultry* arriving at the processing plant with broken bones and/or dislocated joints should be recorded in a manner that allows for verification. For *poultry*, the percentage of chickens with broken or dislocated wings should not exceed 2%, with less than 1% being the goal (under study).

EU Comment

The EU wishes to reiterate its previous comment.

In the last two paragraphs of point 2) of Art 7.5.2, the word "visible" should be included before the words "broken bones". In addition the expression "and severe bruising" should be added on the same sentence.

Justification

Broken bones in poultry are not always visible. Severe bruising is also a visible sign of improper handling.

3. Provisions relevant to animals delivered in containers

a) *Containers* in which *animals* are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded and unloaded

mechanically, and stacked to ensure ventilation. In any case they should be moved and stored in an upright position as indicated by specific marks.

b) *Animals* delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, *animals* should be unloaded from the *containers* individually.

c) *Animals* which have been transported in *containers* should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of *slaughter* should have drinking water available to them from appropriate facilities at all times. Delivery of *poultry* for *slaughter* should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. *Animals* which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

4. Provisions relevant to restraining and containing animals

a) Provisions relevant to *restraining animals* for *stunning* or *slaughter* without *stunning*, to help maintain *animal welfare*, include:

i) provision of a non-slippery floor;

EU Comment

In the above point 4.a) i) of Art 7.5.2, the words "*and level*" should be added after the words "*non-slippery*".

Justification

A level floor allows cattle to stand in a stable manner whilst bleeding. Unlevel (stepped) floors tend to cause unnecessary agitation and movement impacting on the bleeding process.

ii) avoidance of excessive pressure applied by restraining equipment that causes struggling or vocalisation in animals;

iii) equipment engineered to reduce noise of air hissing and clanging metal;

iv) absence of sharp edges in *restraining* equipment that would harm *animals*;

v) avoidance of jerking or sudden movement of restraining device;

vi) the restrainer should not look like a dead end.

b) Methods of *restraint* causing avoidable suffering should not be used in conscious *animals* because they cause severe pain and stress:

i) suspending or hoisting *animals* (other than *poultry*) by the feet or legs;

ii) indiscriminate and inappropriate use of *stunning* equipment;

iii) mechanical clamping of the legs or feet of the *animals* (other than shackles used in *poultry* and ostriches) as the sole method of *restraint*;

iv) breaking legs, cutting leg tendons or blinding *animals* in order to immobilise them;

v) severing the spinal cord, for example using a puntilla or dagger, to immobilise *animals* using electric currents to immobilise *animals*, except for proper *stunning*.

Lairage design and construction

1. General considerations

The *lairage* should be designed and constructed to hold an appropriate number of *animals* in relation to the throughput rate of the *slaughterhouse* without compromising the *welfare* of the *animals*.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the *animals*, the *lairage* should be designed and constructed so as to allow the *animals* to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following recommendations may help to achieve this.

2. Design of lairage

a) The *lairage* should be designed to allow a one-way flow of *animals* from *unloading* to the point of *slaughter*, with a minimum number of abrupt corners to negotiate.

b) In red meat *slaughterhouses*, pens, passageways and races should be arranged in such a way as to permit inspection of *animals* at any time, and to permit the removal of sick or injured *animals* when considered to be appropriate, for which separate appropriate accommodation should be provided.

c) Each *animal* should have room to stand up and lie down and, when confined in a pen, to turn around, except where the *animal* is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious *animals* should be slaughtered as soon as possible after arrival at the *slaughterhouse* to avoid *welfare* problems. The *lairage* should have sufficient accommodation for the number of *animals* intended to be held. Drinking water should always be available to the *animals*, and the method of delivery should be appropriate to the type of *animal* held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in *animals*, and should not hinder the movement of *animals*.

EU comment

The EU would like to reiterate its previous comment.

In point 2c) of Art 7.5.3, the text "*confined in pen*" should be replaced by "*kept in group*"

Justification

New systems are used where bovine animals are kept individually, able to stand up and lie down but still are able to see, hear, and smell each other, are developed for safety reasons and may be used. The animals can still feel that they are part of a group in those systems.

d) Holding pens should be designed to allow as many *animals* as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all *animals* to feed. The feed trough should not hinder the movement of *animals*.

e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the *animals* and should also allow the *animals* to stand, lie down and access any food or water that may need to be provided.

f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent *animals* to see each other. For pigs and sheep, passageways should be wide enough to enable two or more *animals* to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the *animals*.

g) *Animal handlers* should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of *animals* to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of *animals* without injury.

h) In slaughterhouses with high throughput, t~~T~~here should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of *stunning* or *slaughter*, to ensure a steady supply of *animals* for *stunning* or *slaughter* and to avoid having *animal handlers* trying to rush *animals* from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that *animals* cannot be trapped or trampled.

i) Ramps or lifts should be used for the *loading* and *unloading* of *animals* where there is a difference in height or a gap between the floor of the *vehicle* and the *unloading* area. Unloading ramps should be designed and constructed so as to permit *animals* to be unloaded from *vehicles* on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent *animals* escaping or falling. They should be well drained, with secure footholds and adjustable to facilitate easy movement of *animals* without causing distress or injury.

3. Construction of lairage

a) *Lairages* should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the *animals*.

b) Floors should be well drained and not slippery; they should not cause injury to the feet of the *animals*. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where *animals* would have to cross them. Discontinuities or changes in floor, wall or gate, colour, patterns or texture which could cause baulking in the movement of *animals* should be avoided.

c) *Lairages* should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the *animals* or affect their movement. The fact that *animals* will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.

d) *Lairages* should be adequately ventilated to ensure that waste gases (e.g. ammonia) do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of *animals* the *lairage* will be expected to hold.

e) Care should be taken to protect the *animals* from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noises to the areas where *animals* are held and slaughtered.

f) Where *animals* are kept in outdoor *lairages* without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 7.5.4.

Care of animals in lairages

Animals in *lairages* should be cared for in accordance with the following recommendations:

1. As far as possible, established groups of *animals* should be kept together. Each *animal* should have enough space to stand up, lie down and turn around. *Animals* hostile to each other should be separated.

EU comment

The EU would like to reiterate its previous comment.

In point 1 of Art 7.5.4, the text "when kept in group," should be added in the following sentence as follows:

"Each animal should have enough space to stand up, lie down and, when kept in group, turn around."

Justification

See previous comment in Art 7.5.3 point 2) c).

2. Where tethers, ties or individual stalls are used, they should allow *animals* to stand up and lie down without causing injury or distress.

3. Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the *animals*, and sufficient bedding should be used so that *animals* do not become soiled with manure.

4. *Animals* should be kept securely in the *lairage*, and care should be taken to prevent them from escaping and from predators.

5. Suitable drinking water should be available to the *animals* on their arrival and at all times to *animals* in *lairages* unless they are to be slaughtered without delay.

6. If *animals* are not to be slaughtered within 12 hours of their arrival ~~as soon as possible~~, suitable feed should be available to the *animals* on arrival and at intervals appropriate to the species. Unweaned *animals* should be slaughtered as soon as possible.

7. In order to prevent heat stress, *animals* subjected to high temperatures, particularly pigs and *poultry*, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of *animals* to thermoregulate (especially *poultry*) should be considered in any decision to use water sprays. The risk of *animals* being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.

8. The *lairage* area should be well lit in order to enable the *animals* to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all *animals*. Subdued lighting, and for example blue light, may be useful in *poultry lairages* in helping to calm birds.

9. The condition and state of health of the *animals* in a *lairage* should be inspected at least every morning and evening by a *veterinarian* or, under the *veterinarian*'s responsibility, by another competent person, such as an *animal handler*. *Animals* which are sick, weak, injured or showing visible signs of distress should be separated, and veterinary advice should be sought immediately regarding treatment or the *animals* should be humanely killed immediately if necessary.

10. Lactating dairy *animals* should be slaughtered as soon as possible. Dairy *animals* with obvious udder distension should be milked to minimise udder discomfort.

11. *Animals* which have given birth during the *journey* or in the *lairage* should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for their *welfare* and the *welfare* of the newborn. Under normal circumstances, *animals* which are expected to give birth during a *journey* should not be transported.

12. *Animals* with horns, antlers or tusks capable of injuring other *animals*, if aggressive, should be penned separately.

13. *Poultry* awaiting *slaughter* should be protected from adverse weather conditions and provided with adequate ventilation.

14. Waiting time should be minimised and should not exceed 12 hours when no food or water is provided during waiting.

15. *Poultry* in transport *containers* should be examined at the time of arrival. *Containers* should be stacked with sufficient space between the stacks to facilitate inspection of birds and air movement.

16. Forced ventilation or other cooling systems may be necessary under certain conditions to avoid build up of temperature and humidity. Temperature and humidity should be monitored at appropriate intervals.

Recommendations for specific species are described in detail in Articles 7.5.5. to 7.5.9.

Article 7.5.5.

Management of foetuses during slaughter of pregnant animals

Under normal circumstances, pregnant *animals* that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately, and the specific procedures described below are applied. In all cases, the *welfare* of foetuses and dams during *slaughter* should be safeguarded.

Foetuses should not be removed from the uterus sooner than 5 minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-*slaughter* processing of pregnant *animals*, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15–20 minutes after the maternal neck or chest cut.

If there is any doubt about consciousness, the foetus should be killed with a captive bolt of appropriate size or a blow to the head with a suitable blunt instrument.

The above recommendations do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at the evisceration of the dam, should not be attempted during normal commercial *slaughter* as it may lead to serious *welfare* complications in the newborn *animal*. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

Article 7.5.6.

Summary analysis of handling and restraining methods and the associated animal welfare issues

	Presentation of animals	**Specific procedure**	**Specific purpose**	**Animal welfare concerns/ implications**	**Key animal welfare requirements**	**Applicable species**
No restraint	Animals are grouped	Group container	Gas stunning	Specific procedure is suitable only for gas stunning	Competent animal handlers in lairage; facilities; stocking density	Pigs, poultry
		In the field	Free bullet	Inaccurate targeting and inappropriate ballistics not achieving outright kill with first shot	Operator competence	Deer
		Group stunning pen	Head-only electrical Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and mechanical stunning methods	Competent animal handlers in lairage and at stunning point	Pigs, sheep, goats, calves
	Individual animal confinement	Stunning pen/box	Electrical and mechanical stunning methods	Loading of animal; accuracy of stunning method, slippery floor and animal falling down	Competent animal handlers	Cattle, buffalo, sheep, goats, horses, pigs, deer, camelids, ratites
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent animal handlers	Cattle, buffalo, horses, camelids
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent animal handlers, prompt stunning or slaughter	Cattle
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent animal handler	Breeding pigs (boars and sows)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
	Upright restraint	Beak holding	Captive bolt Electrical-head only	Stress of capture	Sufficient competent animal handlers	Ostriches
		Head restraint in electrical stunning box	Electrical-head only	Stress of capture and positioning	Competent animal handler	Ostriches
	Holding body upright- manual	Manual restraint	Captive bolt Electrical-head only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/ slaughter	Competent animal handlers	Sheep, goats, calves, ratites, small camelids, poultry
	Holding body upright mechanical	Mechanical clamp / crush / squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint – manual or mechanical	Restrainer/ cradle/crush	Slaughter without stunning	Stress of restraint	Competent animal handlers	Sheep, goats, calves, camelids, cattle
	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining methods (contd)	Upright restraint mechanical	Mechanical straddle (static)	Slaughter without stunning Electrical methods Captive bolt	Loading of animal and overriding	Competent animal handlers	Cattle, sheep, goats, pigs
	Upright restraint – manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent animal handlers	Ostriches
Restraining and /or conveying methods	Mechanical - upright	V-restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
	Mechanical-upright	Mechanical straddle – band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical - upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones; Keep restraint as short as possible	Competent animal handlers; proper design and operation of equipment; birds should be hung by both legs	Poultry
	Suspension and/or inversion	Cone	Electrical – head-only Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg pen)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint, inhalation of blood and ingesta Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint Preferable to rotating box with fixed sides Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Body restraint	Casting/ hobbling	Manual	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, calves, small camelids, pigs
Leg restraints		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Cattle, camelids
		Tying of 3 or 4 legs	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Sheep, goats, small camelids, pigs

Article 7.5.7.

Stunning methods

1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for *stunning* and the maintenance of the equipment are the responsibility of the management of the *slaughterhouse*, and should be checked regularly by a *Competent Authority*.

Persons carrying out *stunning* should be properly trained and competent, and should ensure that:

a) the *animal* is adequately restrained;

b) *animals* in *restraint* are stunned as soon as possible;

EU comment

The EU would like to reiterate its previous comment.

In Article 7.5.7 (1) (b), the following text should be included: "*animals should not be restrained until the personnel carrying out the stunning is ready to do so*."

Justification

Maintaining the animal in the restraining equipment increases the stress of the animal.

c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the *animal*;

d) the equipment is applied correctly;

e) stunned *animals* are bled out (slaughtered) as soon as possible;

f) *animals* are not stunned when *slaughter* is likely to be delayed; and

g) backup *stunning* devices are available for immediate use if the primary method of *stunning* fails. Provision of a manual inspection area and simple intervention like captive bolt and cervical dislocation for *poultry* would help prevent potential *welfare* problems.

EU comment

The EU would like to reiterate its previous comment.

In point 1.g) of Article 7.5.7, the text "*like captive bolt and cervical dislocation*" should be replaced by "*like captive bolt which is more humane than cervical dislocation*".

Justification

In the EFSA opinion from 15 June 2004 it is stated that neck dislocation may not concuss poultry and it is therefore uncertain whether it causes immediate unconsciousness.

In addition, such persons should be able to recognise when an *animal* is not correctly stunned and should take appropriate action.

2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. For a more detailed explanation on the different methods for mechanical *stunning*, see Chapter 7.6. and Articles 7.6.6., 7.6.7. and 7.6.8. The following diagrams illustrate the proper application of the device for certain species.

Cattle

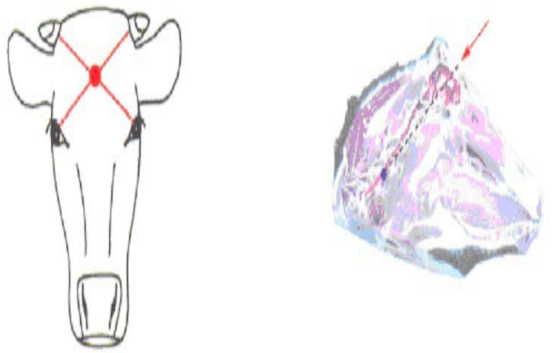

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Pigs

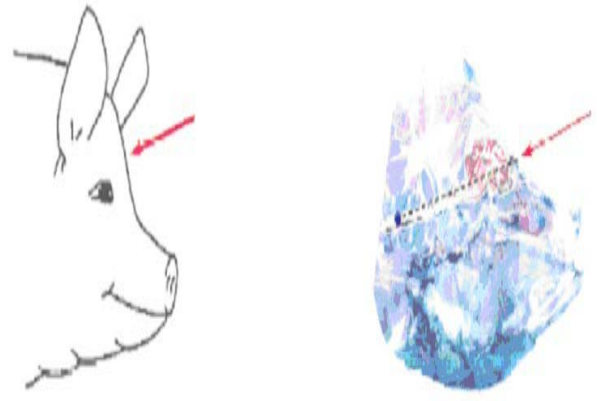

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

Sheep

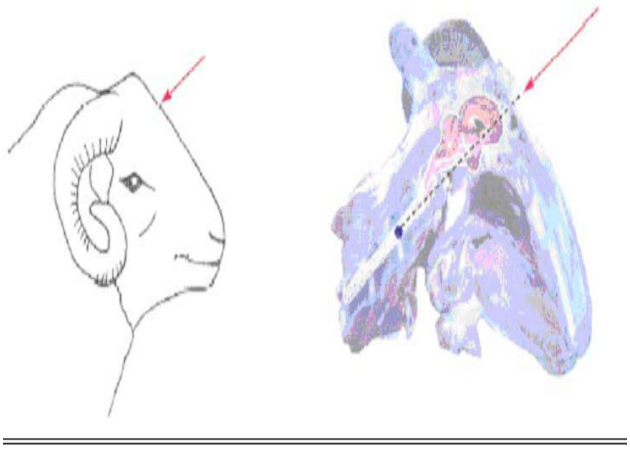

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for hornless sheep and goats is on the midline.

Goats

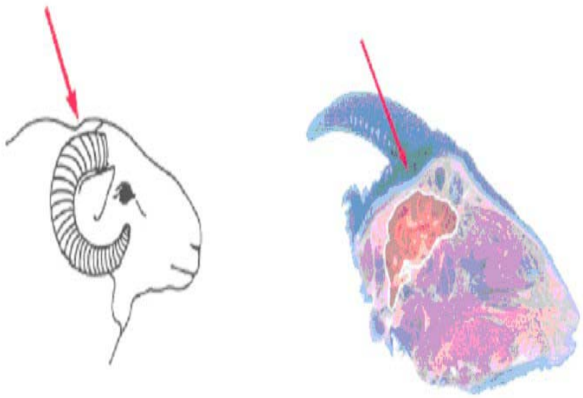

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

Horses

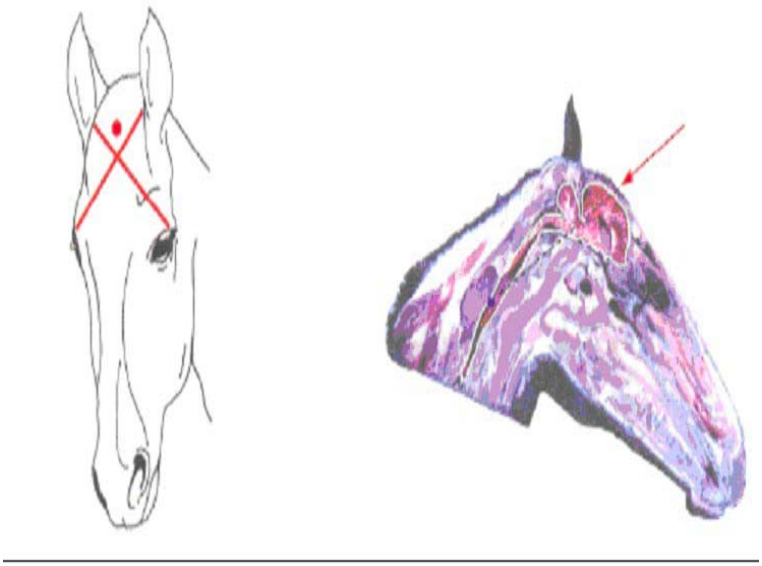

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Signs of correct *stunning* using a mechanical instrument are as follows:

a) the *animal* collapses immediately and does not attempt to stand up;

b) the body and muscles of the *animal* become tonic (rigid) immediately after the shot;

c) normal rhythmic breathing stops; and

d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

Poultry

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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Poultry

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at right angles to the frontal surface.

Firing of a captive bolt according to the manufacturers' instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate *death*.

3. Electrical stunning

a) General considerations

An electrical device should be applied to the *animal* in accordance with the following recommendations.

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the *animal* has been stunned. The use of a single current leg-to-leg is unacceptable as a *stunning* method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the *animal* is adequately stunned, or span brain and heart simultaneously.

Electrical *stunning* equipment should not be applied on *animals* as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the *animal* before the actual *stunning* or *killing*.

Electrical *stunning* apparatus should be tested prior to application on *animals* using appropriate resistors or dummy loads to ensure the power output is adequate to stun *animals*.

The electrical *stunning* apparatus should incorporate a device that monitors and displays voltage (true RMS) and the applied current (true RMS) and that such devices are regularly calibrated at least annually.

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective *stunning*.

The *stunning* apparatus should be appropriate for the species. Apparatus~~required~~ for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below.

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions. Minimum current levels for head-only *stunning* are shown in the following table.

Species	Minimum current levels for head-only stunning
Cattle	1.5 amps
Calves (bovines of less than 6 month of age)	1.0 amps
Pigs	1.25 amps
Sheep and goats	1.0 amps
Lambs	0.7 amps
Ostriches	0.4 amps

b) Electrical stunning of birds using a waterbath

There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks.

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks. The shackle size should be appropriate to fit the size of the shanks (metatarsal bones) of birds.

Birds should be hung on shackles by both legs.

Birds with dislocated or broken legs or wings should be humanely killed rather than shackled.

The duration between hanging on shackles and *stunning* should be kept to the minimum. In any event, the time between shackling and *stunning* should not exceed one minute.

Waterbaths for *poultry* should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

EU Comment

The EU would like to reiterate its previous comment.

In Art 7.5.7 point 3.b), the following sentence should be added in the above paragraph:

"The entrance to the water bath should be designed in a way which prevents pre-stun shocks."

The waterbath should be designed and maintained in such a way that when the shackles pass over the water, they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve the electrical conductivity of the water, it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

While a lower current may also be satisfactory, the current shall in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents ~~may~~ should be required.

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of *stunning* and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of birds that have not been effectively stunned reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately. The height of the waterbath stunner should be adjusted according to the size of birds to ensure even the small birds are immersed in the water bath up to the base of the wings.

Waterbath *stunning* equipment should be fitted with a device which displays and records the details of the electrical key parameter.

Minimum current for *stunning poultry* when using 50Hz is as follows:

Minimum current for *stunning poultry* when using high frequencies is as follows:

Species	Current (milliamperes per bird)
Broilers	100
Layers (spent hens)	100
Turkeys	150
Ducks and geese	130
	Minimum current (milliamperes per bird)

Frequency (Hz)	Chickens	Turkeys
From 50 to < 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

3. Gas stunning (under study)

EU comment

The above point should be numbered as 4.

a) Stunning of pigs by exposure to carbon dioxide (CO_2)

The concentration of CO_2 for *stunning* should be preferably 90% by volume but in any case no less than 80% by volume. After entering the *stunning* chamber, the *animals* should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until *death* occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO_2 for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the *animal* prior to loss of consciousness.

The chamber in which *animals* are exposed to CO_2 and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the *animals*. The animal density within the chamber should be such to avoid stacking *animals* on top of each other.

The conveyor and the chamber shall be adequately lit to allow the *animals* to see their surroundings and, if possible, each other.

It should be possible to inspect the CO_2 chamber whilst it is in use, and to have access to the *animals* in emergency cases.

EU comment

The EU would like to reiterate its previous comment.

We suggest deleting this paragraph above "*It should be possible to inspect the CO2 chamber whilst it is in use, and to have access to the animals in emergency cases*."

Justification

Practically there is no simple way to inspect CO2 chambers when it is in use and due to the gas concentration human intervention is unlikely to be performed any way.

The chamber shall be equipped to continuously measure and display register at the point of *stunning* the CO_2 concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO_2 falls below the required level.

Emergency *stunning* equipment should be available at the point of exit from the *stunning* chamber and used on any pigs that do not appear to be ~~dead or~~ completely stunned.

b) Inert gas mixtures for stunning pigs

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to *animals*. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

i) a maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or

ii) to a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas *stunning* is to avoid the pain and suffering associated with shackling conscious *poultry* under water bath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to *poultry*.

Live *poultry* contained within transport modules or crates may be exposed to gradually increasing concentrations of CO_2 until the birds are properly stunned. No bird should recover consciousness during bleeding.

Gas *stunning* of *poultry* in their transport *containers* will eliminate the need for live birds' handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of *poultry* on a conveyor eliminates the problems associated with the electrical water bath *stunning*.

Live *poultry* should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all *animals* are properly stunned without unnecessary suffering. Some monitoring points for gas *stunning* could be the following:

- ensure smooth entry and passage of crates or birds through the system;
- avoid crowding of birds in crates or conveyors;
- monitor and maintain gas concentrations continuously during operation;
- provide visible and audible alarm systems if gas concentrations are inappropriate to the species;
- calibrate gas monitors and maintain verifiable records;
- ensure that duration of exposure is adequate to prevent recovery of consciousness;
- make provision to monitor and deal with recovery of consciousness;
- ensure that blood vessels are cut to induce *death* in unconscious birds;
- ensure that all birds are dead before entering scalding tank;
- provide emergency procedures in the event of system failure.

i) Gas mixtures used for stunning *poultry* include:

- a minimum of 2 minutes exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of one minute exposure to 80% carbon dioxide in air; or
- a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not

exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or

- a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or
- a minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air; or
- a minimum of one minute exposure to 30% carbon dioxide in air, followed by a minimum of one minute exposure to at least 60% carbon dioxide in air.

ii) Requirements for effective use are as follows:

- Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock; under no circumstances, should solid gases with freezing temperatures enter the chamber.
- Gas mixtures should be humidified.
- Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

4. Bleeding

EU comment

The above point should be numbered as 5.

From the point of view of *animal welfare*, *animals* which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the *stunning* method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the *slaughterhouse* operator should set up a maximum stun-stick interval that ensures that no *animals* recover consciousness during bleeding. In any case the following time limits should be applied.

EU comment

The EU would like to reiterate its previous comment.

In point 5 of Art 7.5.7, the following text should be added at the end of the paragraph above:

"*The stun-stick interval should commence from when the animal collapses into the tonic phase when stunned by electricity*."

Justification

It is important that precisely specify the starting point of the stun-to-stick interval

All *animals* should be bled out by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the *stunning* method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of view of *animal welfare*.

It should be possible for staff to observe, inspect and access the *animals* throughout the bleeding period. Any *animal* showing signs of recovering consciousness should be re-stunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the *animals* for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

Stunning method	**Maximum delay for bleeding to be started**
Electrical methods and non-penetrating captive bolt	20 seconds
CO_2	60 seconds (after leaving the chamber)

EU comment

The EU would like to reiterate its previous comment.

In the table in point 5 of Art 7.5.7, the wording "*Maximum delay for bleeding to be started*" should be replaced by "*Maximum stun –stick interval*" since it is more consistent with the wording of the text.

Moreover the row related to CO2 should be deleted since the stun-stick interval is in this case highly dependent on the stunning protocol used (concentration and duration of exposure) leading to a false security.

Article 7.5.8.

Summary analysis of stunning methods and the associated animal welfare issues

Method	**Specific method**	**Animal welfare concerns/ implications**	**Key animal welfare requirements applicable**	**Species**	**Comment**
Mechanical	Free bullet	Inaccurate targeting and inappropriate ballistics	Operator competence; achieving outright kill with first shot	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
	Captive bolt - penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites, poultry	(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot
	Captive bolt - non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites, poultry	Presently available devices are not recommended for young bulls and animals with thick skull. This method should only be used for cattle and sheep when alternative methods are not available.
	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent animal handlers; restraint; accuracy. Not recommended for general use	Young and small mammals, ostriches and poultry	Mechanical devices potentially more reliable. Where manual percussive blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used.
	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	
Gaseous	CO_2 air/O_2 mixture; CO_2 inert gas mixture	Aversiveness of high CO_2; respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	

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Article 7.5.9.

Summary analysis of slaughter methods and the associated animal welfare issues

Slaughter methods	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut	High level of operator competency. A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	No further procedure should be carried out before the bleeding out is completed (i.e. at least 30 seconds for mammals). The practice to remove hypothetical blood clots just after the bleeding should be discouraged since this may increase animal suffering.
Bleeding with prior stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.	A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats	
	Neck stab followed by forward cut	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Neck stab alone	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	
	Neck skin cut followed by severance of vessels in the neck	Ineffective stunning; inadequate size of stick wound; inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate cutting of vessels	Cattle	
	Automated mechanical cutting	Ineffective stunning; failure to cut and misplaced cuts. Recovery of consciousness following reversible stunning systems	Design, maintenance and operation of equipment; accuracy of cut; manual back-up	Poultry only	
	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning

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Slaughter methods	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka slaughter
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord. Acceptable only when slaughtering small numbers of small birds.
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Article 7.5.10.

Methods, procedures or practices unacceptable on animal welfare grounds

1. The restraining methods which work through immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in *animals*. Those methods are not acceptable in any species.

EU comment

The EU would like to reiterate its previous comment.

Under point 1 of Article 7.5.10, the sentence should be amended as follows:

"The restraining methods which work through electro-immobilisation or immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in animals. Those methods are not acceptable in any species."

Justification

Use of electricity for immobilisation is not acceptable from an animal welfare point of view.

2. The use of the electrical *stunning* method with a single application leg to leg is ineffective and unacceptable in any species.

3. The *slaughter* method of brain stem severance by piercing through the eye socket or skull bone without prior *stunning* is not acceptable in any species.

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CHAPTER 7.6.

KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

EU comments

The EU acknowledges the work carried out by the OIE to improve the chapter.

The EU wishes to reiterate some previous comments given their relevance.

Article 7.6.1.

General principles

These recommendations are based on the premise that a decision to kill the *animals* has been made, and address the need to ensure the *welfare* of the *animals* until they are dead.

1. All personnel involved in the humane *killing* of *animals* should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience.
2. As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from *animal welfare*, aesthetics of the method of euthanasia, cost of the method, operator safety, biosecurity and environmental aspects.
3. Following the decision to kill the *animals*, *killing* should be carried out as quickly as possible, and normal husbandry should be maintained until the *animals* are killed.
4. The handling and movement of *animals* should be minimised and when done, it should be carried out ~~done~~ in accordance with the recommendations described below.
5. Animal *restraint* should be sufficient to facilitate effective *killing*, and in accordance with *animal welfare* and operator safety requirements; when *restraint* is required, *killing* should follow with minimal delay.
6. When *animals* are killed for disease control purposes, methods used should result in immediate *death* or immediate loss of consciousness lasting until *death*; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive or the least aversive possible and should not cause avoidable anxiety, pain, distress or suffering in *animals*.
7. For *animal welfare* considerations, young *animals* should be killed before older *animals*; for biosecurity considerations, infected *animals* should be killed first, followed by in-contact *animals*, and then the remaining *animals*.
8. There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to *animal welfare*, operator safety and biosecurity.
9. When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on *animal welfare*, operator safety and biosecurity.
10. These general principles should also apply when *animals* need to be killed for other purposes such as after natural disasters or for culling animal populations.

Article 7.6.2.

Organisational structure

Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; *animal welfare* considerations should be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel competent in the humane *killing* of *animals* is available. Local level plans should be based on national plans and be informed by local knowledge.

Disease control contingency plans should address the *animal welfare* issues that may result from animal movement controls.

The operational activities should be led by an *official Veterinarian* who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required *animal welfare* and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved have the required competencies.

The *official Veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The *official Veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE *animal welfare* and animal health recommendations.

A specialist team, led by a team leader answerable to the *official Veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a *veterinarian* or have access to veterinary advice at all times.

In considering the *animal welfare* issues associated with *killing animals*, the key personnel, their responsibilities and competencies required are described in Article 7.6.3.

Article 7.6.3.

Responsibilities and competencies of the specialist team

1. Team leader
   a) Responsibilities
      i) plan overall operations on affected premises;
      ii) determine and address requirements for *animal welfare*, operator safety and biosecurity;
      iii) organise, brief and manage team of people to facilitate humane *killing* of the relevant *animals* on the premises in accordance with national regulations and these recommendations;
      iv) determine logistics required;
      v) monitor operations to ensure *animal welfare*, operator safety and biosecurity requirements are met;
      vi) report upwards on progress and problems;
      vii) provide a written report at the conclusion of the *killing*, describing the practices adopted and their effect on the *animal welfare*, operator safety and biosecurity outcomes.
   b) Competencies
      i) appreciation of normal animal husbandry practices;
      ii) appreciation of *animal welfare* and the underpinning behavioural, anatomical and physiological processes involved in the *killing* process;

iii) skills to manage all activities on premises and deliver outcomes on time;

iv) awareness of psychological effects on farmer, team members and general public;

v) effective communication skills;

vi) appreciation of the environmental impacts caused by their operation.

2. Veterinarian

a) Responsibilities

i) determine and supervise the implementation of the most appropriate *killing* method to ensure that *animals* are killed without avoidable pain and distress;

ii) determine and implement the additional requirements for *animal welfare*, including the order of *killing*;

iii) ensure that confirmation of the *death* of the *animals* is carried out by competent persons at appropriate times after the *killing* procedure;

iv) minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures;

v) continuously monitor *animal welfare* and biosecurity procedures;

vi) in cooperation with the leader, prepare a written report at the conclusion of the *killing*, describing the practices adopted and their effect on *animal welfare*.

b) Competencies

i) ability to assess *animal welfare*, especially the effectiveness of *stunning* and *killing* and to correct any deficiencies;

ii) ability to assess biosecurity risks.

3. Animal handlers

a) Responsibilities

i) review on-site facilities in terms of their appropriateness;

ii) design and construct temporary animal handling facilities, when required;

iii) move and restrain *animals*;

iv) continuously monitor *animal welfare* and biosecurity procedures.

b) Competencies

i) animal handling in emergency situations and in close confinement is required;

ii) an appreciation of biosecurity and containment principles.

4. Animal killing personnel

a) Responsibilities

Humane *killing* of the *animals* through effective *stunning* and *killing* should be ensured.

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b) Competencies

i) when required by regulations, licensed to use necessary equipment;

ii) competent to use and maintain relevant equipment;

iii) competent to use techniques for the species involved;

iv) competent to assess effective *stunning* and *killing*.

5. Carcass disposal personnel

a) Responsibilities

An efficient carcass disposal (to ensure *killing* operations are not hindered) should be ensured.

b) Competencies

The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager

a) Responsibilities

i) assist when requested.

b) Competencies

ii) specific knowledge of his/her animals and their environment.

Article 7.6.4.

Considerations in planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane *killing* of *animals*. The team leader should develop a plan for humanely *killing animals* on the premises which should include consideration of:

1. minimising handling and movement of *animals*;
2. *killing* the *animals* on the affected premises; however, there may be circumstances where the *animals* may need to be moved to another location for *killing*; when the *killing* is conducted at an *abattoir*, the recommendations in Chapter 7.5. on the *slaughter* of *animals* should be followed;
3. the species, number, age and size of *animals* to be killed, and the order of *killing* them;
4. methods of *killing* the *animals*, and their cost;
5. housing, husbandry, location of the *animals* as well as accessibility of the farm;
6. the availability and effectiveness of equipment needed for *killing* of the *animals*, as well as the time necessary to kill the required number of *animals* using such methods;
7. the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;
8. biosecurity and environmental issues;

9. the health and safety of personnel conducting the *killing*;
10. any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;
11. the presence of other nearby premises holding *animals*;
12. possibilities for removal, disposal and destruction of carcasses.

The plan should minimise the negative *welfare* impacts of the *killing* by taking into account the different phases of the procedures to be applied for *killing* (choice of the *killing* sites, *killing* methods, etc.) and the measures restricting the movements of the *animals*.

Competences and skills of the personnel handling and *killing animals*.

In designing a *killing* plan, it is essential that the method chosen be consistently reliable to ensure that all *animals* are humanely and quickly killed.

Article 7.6.5.

Table summarising killing methods described in Articles 7.6.6.-7.6.18.

EU Comment

The methods of cervical dislocation and decapitation for poultry should be included in the table of Art 7.6.5.

Justification

These methods are referred to in Art 7. 6. 17 as well as in the draft chapter on "*Animal Welfare and broiler chicken production*".

The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an *animal welfare* viewpoint.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle	all	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt - followed by pithing or bleeding	yes	ineffective stunning	7.6.7.
	adults only	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	7.6.8.
	calves only	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	calves only	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
Sheep and goats	all	free bullet	no	non-lethal wounding	7.6.6.
Sheep and goats (contd)	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.7.
	all except neonates	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.8.
	neonates	non-penetrating captive bolt	yes	non-lethal wounding	7.6.8.
	all	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	all	electrical, single application	yes	ineffective stunning	7.6.11.

		(method 1)			
	neonates only	CO_2 / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
Pigs	all, except neonates	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.7.
	neonates only	non-penetrating captive bolt	yes	non-lethal wounding	7.6.8.
	all[1]	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	neonates only	CO_2 / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	7.6.12.
Pigs (contd)	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection with barbiturates and other	yes	non-lethal dose, pain associated with injection site	7.6.15.
Poultry	adults only	non-penetrating captive bolt	yes	ineffective stunning	7.6.8.
	day-olds and eggs only	maceration	no	non-lethal wounding, non-immediacy	7.6.9.
	adults only	electrical, single application (method 2)	yes	ineffective stunning	7.6.11.
	adults only	electrical, single application, followed by killing (method 3)	yes	ineffective stunning; regaining of consciousness before death	7.6.11.
	all	CO_2 / air mixture Method 1 Method 2	 yes no	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	all	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	7.6.16.

Article 7.6.6.

Free bullet

1. Introduction

a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.

b) The most commonly used firearms for close range use are:

i) humane killers (specially manufactured/adapted single-shot weapons);

ii) shotguns (12, 16, 20, 28 bore and .410);

iii) rifles (.22 rimfire);

iv) handguns (various calibres from .32 to .45).

c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).

d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the *animals* (high neck shot) and to cause irreversible concussion and *death* and should only be used by properly trained and competent marksmen.

2. Requirements for effective use

a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.

b) The marksman should ensure that the *animal* is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5 –50 cm for a shotgun) but the barrel should not be in contact with the head of the *animals*.

c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally, the ammunition should expand upon impact and dissipate its energy within the cranium.

d) Shot *animals* should be checked to ensure the absence of brain stem reflexes.

3. Advantages

a) Used properly, a free bullet provides a quick and effective method for *killing*.

b) It requires minimal or no *restraint* and can be use to kill from a distance by properly trained and competent marksmen.

c) It is suitable for *killing* agitated *animals* in open spaces.

4. Disadvantages

a) The method is potentially dangerous to humans and other *animals* in the area.

b) It has the potential for non-lethal wounding.

c) Destruction of brain tissue may preclude diagnosis of some *diseases*.

d) Leakage of bodily fluids may present a biosecurity risk.

e) Legal requirements may preclude or restrict use.

f) There is a limited availability of competent personnel.

5. Conclusion

The method is suitable for cattle, sheep, goats and pigs, including large *animals* in open spaces.

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Annex XIII (contd)

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. The optimum position for hornless sheep and goats is on the midline.

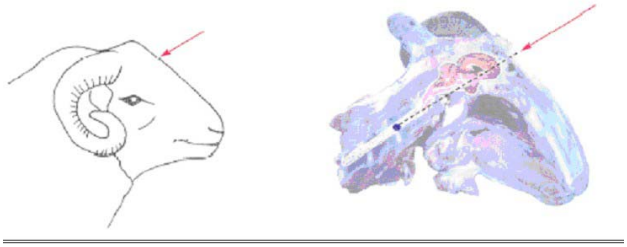

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

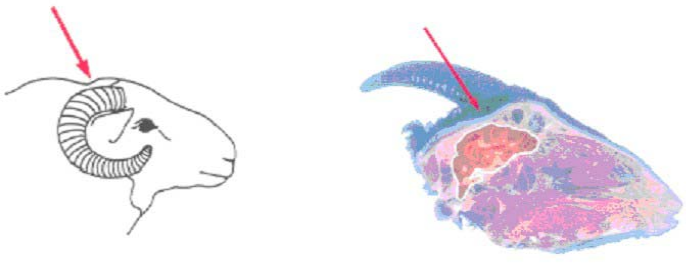

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 4. The optimum shooting position for pigs is just above eye level, with the shot directed down the line of the spinal cord.

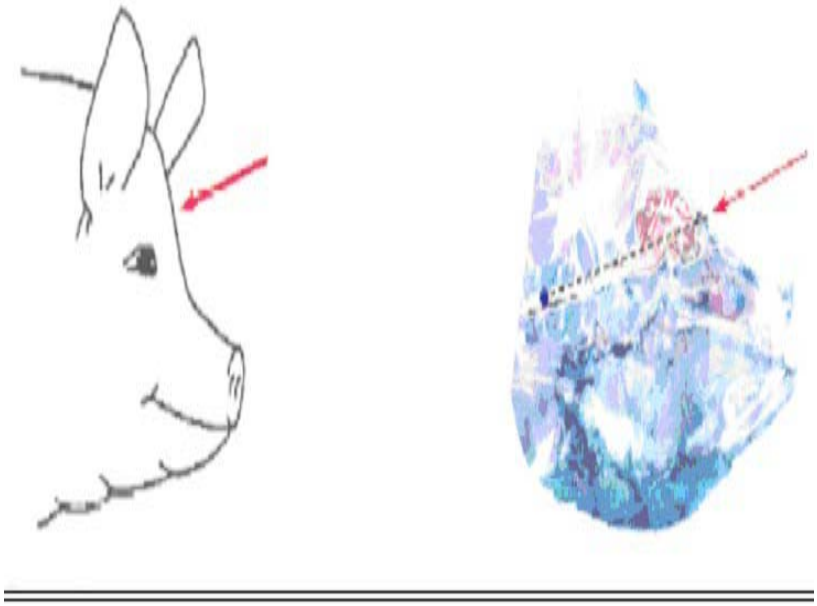

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Article 7.6.7.

Penetrating captive bolt

1. Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the *animal*. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in *death*; however, pithing or bleeding should be performed as soon as possible after the shot to ensure the *death* of the *animal*. Shooting *poultry* species with the captive bolts results in immediate destruction of the skull and brain, causing *death*. For a detailed description on the use of this method, see Chapter 7.5. of the *Terrestrial Code*.

2. Requirements for effective use

a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.

d) *Animals* should be restrained; at a minimum, they should be penned for cartridge powered guns and in a race for compressed air guns.

e) The operator should ensure that the head of the *animal* is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).

g) To ensure the *death* of the *animal*, pithing or bleeding should be performed as soon as possible after *stunning*.

h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

a) Mobility of cartridge powered equipment reduces the need to move *animals*.

b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages

a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.

b) Post stun convulsions may make pithing difficult and hazardous.

c) The method is difficult to apply in agitated *animals*.

d) Repeated use of a cartridge powered gun may result in over-heating.

e) Leakage of bodily fluids may present a biosecurity risk.

f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

5. Conclusions

The method is suitable for *poultry*, cattle, sheep, goats and pigs (except neonates), when followed by pithing or bleeding.

Article 7.6.8.

Non-penetrating captive bolt

1. Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and *death* in poultry and neonate sheep, goats and pigs. Bleeding should be performed as soon as possible after the blow to ensure the *death* of the *animal*.

2. Requirements for effective use

a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.

d) *Animals* should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.

e) The operator should ensure that the head of the *animal* is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1–4).

g) To ensure *death* in non-neonate mammals, bleeding should be performed as soon as possible after *stunning*.

h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

a) The method induces an immediate onset of unconsciousness, and *death* in birds and neonates.

b) Mobility of equipment reduces the need to move *animals*.

4. Disadvantages

a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after *stunning*.

b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.

c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.

d) Post stun convulsions may make bleeding difficult and hazardous.

e) Difficult to apply in agitated *animals*; such *animals* may be sedated in advance of the *killing* procedure.

f) Repeated use of a cartridge powered gun may result in over-heating.

g) Bleeding may present a biosecurity risk.

5. Conclusions

The method is suitable for *killing* poultry, and neonate sheep, goats and pigs up to a maximum weight of 10 kg.

Article 7.6.9.

Maceration

1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and *death* in day-old *poultry* and embryonated eggs.

Annex XIII (contd)

2. Requirements

a) Maceration requires specialised equipment which should be kept in excellent working order.

b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

3. Advantages

a) Procedure results in immediate *death*.

b) Large numbers can be killed quickly.

4. Disadvantages

a) Specialised equipment is required.

b) Macerated tissues may present biosecurity or human health risks.

c) The cleaning of the equipment can be a source of contamination.

5. Conclusion

The method is suitable for *killing* day-old poultry and embryonated eggs.

Article 7.6.10.

Electrical – two-stage application

1. Introduction

A two-stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce 'tonic/clonic' epilepsy and unconsciousness. Once the *animal* is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in *death*. The second stage (the application of low frequency current across the chest) should only be applied to unconscious *animals* to prevent unacceptable levels of pain.

2. Requirements for effective use

a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:

Animal	**Minimum voltage (V)**	**Minimum current (A)**
Cattle	220	1.5
Sheep	220	1.0
Pigs over 6 weeks of age	220	1.3
Pigs less than 6 weeks of age	125	0.5

b) Appropriate protective clothing (including rubber gloves and boots) should be worn.

c) *Animals* should be restrained, at a minimum free-standing in a pen, close to an electrical supply.

d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the *animal* to allow the second application to be made.

e) A *stunning* current should be applied via scissor-type *stunning* tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.

f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

g) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete.

3. Advantages

a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.

b) Non-invasive technique minimises biosecurity risk.

4. Disadvantages

a) The method requires a reliable supply of electricity.

b) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.

c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).

d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).

Article 7.6.11.

Electrical – single application

1. Method 1

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the *animal* and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the *animal* will not recover consciousness.

Annex XIII (contd)

a) Requirements for effective use

i) The stunner control device should generate a low frequency (30–60 Hz) current with a minimum voltage of 250 volts true RMS under load.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) *Animals* should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the *stunning* electrodes and the *animal* is necessary for effective use.

iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds.

v) Electrodes should be cleaned regularly between *animals* and after use, to enable optimum electrical contact to be maintained.

vi) Water or saline may be necessary to improve electrical contact with sheep.

viii) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

i) Method 1 stuns and kills simultaneously.

ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.

iii) A single team member only is required for the application.

iv) Non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 1 requires individual mechanical animal *restraint*.

ii) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.

iii) Method 1 requires a reliable supply of electricity.

d) Conclusion

Method 1 is suitable for calves, sheep, goats, and pigs (over one week of age).

2. Method 2

Method 2 stuns and kills by drawing inverted and shackled poultry through an electrified waterbath stunner. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, poultry will be simultaneously stunned and killed.

a) Requirements for effective use

i) A mobile waterbath stunner and a short loop of processing line are required.

ii) A low frequency (50–60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.

iii) Poultry need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed.

iv) The required minimum currents to stun and kill dry birds are:

- Quails – 100 mA/bird
- Chickens – 160 mA/bird
- Ducks & geese – 200 mA/bird
- Turkeys – 250 mA/bird.

A higher current is required for wet birds.

v) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

i) Method 2 stuns and kills simultaneously.

ii) It is capable of processing large numbers of birds reliably and effectively.

iii) This non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 2 requires a reliable supply of electricity.

ii) Handling, inversion and shackling of birds are required.

d) Conclusion

Method 2 is suitable for large numbers of poultry.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a *killing* method (see Article 7.6.17.).

a) Requirements for effective use

i) The stunner control device should generate sufficient current (more than 600 mA/duck and more than 300 mA/bird) to stun.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) Birds should be restrained, at a minimum manually, close to an electrical supply.

iv) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

v) Birds should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

b) Advantages

Non-invasive technique (when combined with cervical dislocation) minimises biosecurity risk.

c) Disadvantages

i) Method 3 requires a reliable supply of electricity and is not suitable for large-scale operations.

ii) The electrodes should be applied and maintained in the correct position to produce an effective stun.

iii) Birds should be individually restrained.

iv) It should be followed by a *killing* method.

d) Conclusion

Method 3 is suitable for small numbers of *poultry*.

Article 7.6.12.

CO2 / air mixture

1. Introduction

Controlled atmosphere killing is performed by exposing *animals* to a predetermined gas mixture, either by placing them in a gas-filled *container* or apparatus (Method 1) or by placing transport modules or crates containing birds in a gas tight *container* and introducing a gas mixture (Method 2) or by the gas being introduced into a poultry house (Method 3). Method 2 should be used whenever possible, as it eliminates *welfare* issues resulting from the need to manually remove live birds. Although Method 2 requires handling and crating of the birds, it benefits bird *welfare* overall (in comparison with Method 1) as it reduces the risk of *death* by smothering or suffocation.

Inhalation of carbon dioxide (CO_2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, *death*. Exposure to carbon dioxide does not induce immediate loss of consciousness, therefore the aversive nature of gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase are important considerations for *animal welfare*.

2. Method 1

The *animals* are placed in a gas-filled *container* or apparatus.

a) Requirements for effective use in a *container* or apparatus

i) *Containers* or apparatus should allow the required gas concentration to be maintained and accurately measured.

ii) When *animals* are exposed to the gas individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

iii) *Animals* can also be introduced to low concentrations (as low concentrations are not aversive) and the concentration could be increased afterwards and the *animals* then held in the higher concentration until *death* is confirmed.

iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.

b) Advantages

i) CO_2 is readily available.

ii) Application methods are simple.

iii) The volume of gas required can be readily calculated.

iv) As the units are operated outdoor, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.

v) The system uses skilled catching teams and equipment in daily use by the industry.

vi) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

i) The need for properly designed *container* or apparatus.

ii) The aversive nature of high CO_2 concentrations.

iii) No immediate loss of consciousness.

iv) The risk of suffocation due to overcrowding.

v) Difficulty in verifying *death* while the *animals* are in the *container* or apparatus.

EU comment

In point 2) c) of Article 7.6.12, we suggest adding after (c) (v) the sentence already used for other methods "*However cessation of vocalisations and convulsing wing flapping sounds can be used to determine the onset of unconsciousness that will in due time lead to death*".

Justification

Cessation of vocalizations and convulsing wing flapping sounds occur when the animals become unconscious. Death occurs at a later stage.

There is risk that the birds are taken out of the container too early before the birds are dead.

d) Conclusion

Method 1 is suitable for use in poultry, and neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a chamber into which gas is introduced. As illustrated in the example below, a containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate poultry transport crates or a single module. The chamber is fitted with gas lines and diffusers, with silencers that are connected via a system of manifolds and gas

regulators to gas cylinders. There is a hole at the top to permit displaced air to escape when the *container* is filling with gas.

The procedures for the operation of CGU include (a) position the *container* on level, solid, open ground; (b) connect the gas cylinder to the *container* (c) load birds into the *container* (d) shut and secure the door, (e) deliver the gas until a concentration of 45~~0~~% by volume of carbon dioxide has been achieved at the top of the *container*, (f) allow time for the birds to become unconscious and die (g) open the door and allow gas to be dispersed in the air (h) remove the module (i) check each drawer for survivors (j) humanely kill any survivors; and (k) dispose of carcasses appropriately.

a) Requirements for effective use of containerised gassing units (CGU)

   i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.

   ii) The crates or module full of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas.

   iii) Ensure the *container* door is locked and administer the gas until a minimum concentration of 45~~0~~% carbon dioxide is achieved at the top of the crates.

   iv) An appropriate gas meter should be used to ensure the appropriate concentration of carbon dioxide is achieved and maintained until it can be confirmed that the birds have been killed.

   v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window that allows direct observation of birds during killing, cessation of vocalisation and convulsive wing flapping sounds, which can be listened to by standing near the *container*, can be used to determine that the birds are unconscious and that *death* is imminent. Remove the crates or modules from the *container* and leave them in the open air.

   vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing indicate *death*.

   vii) Any survivors should be humanely killed.

   viii) Ducks and geese are resilient to the effects of carbon dioxide and therefore require a minimum of 80% CO_2 and a longer period of exposure to die.

b) Advantages

   i) The gas is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.

   ii) Gradual increase in the concentration of CO_2 minimises the aversive nature of this method for inducing unconsciousness.

   iii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.

   iv) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.

   v) CO_2 is readily available.

   vi) Birds are exposed to gas more uniformly and they do not smother each other when compared with Method 1.

   vii) The volume of gas required can be readily calculated.

viii) As the units are operated outdoors, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.

ix) The system uses skilled catching teams and equipment in daily use by the industry.

x) Metal *containers* can be readily cleansed and disinfected.

Annex XIII (contd)

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and fork lift. However, this equipment and suitable areas with hard surfaces are usually available.

ii) The main limiting factors are speed of catching birds.

iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping sounds can be used to determine onset of *death*.

iv) The need for properly designed *container* or apparatus

v) No immediate loss of consciousness.

vi) The risk of suffocation due to overcrowding.

d) Conclusion

i) Method 2 is suitable for use in a wide range of poultry systems, providing there is access to *vehicles* to carry the *containers* and equipment.

ii) Birds should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the required gas concentrations, i.e. more than 40% CO_2. Birds are held in this atmosphere until *death* is confirmed.

iii) Method 2 is suitable for use in poultry, and neonatal sheep, goats and pigs. However, CO_2 is likely to cause a period of distress in the *animals* before they lose consciousness.

4. Method 3

The gas is introduced into a poultry house.

a) Requirements for effective use in a poultry house

i) Prior to introduction of the CO_2, the poultry house should be appropriately sealed to allow control over the gas concentration. The interval between sealing and gas administration should be kept to the minimum so as to avoid overheating.

Forced ventilation systems, where fitted, should only be switched off immediately prior to gas administration.

The main water supply to the poultry house may have to be turned off and water drained to avoid freezing and bursting of water pipes.

Feeders and water troughs should be lifted to avoid obstruction of the gas entry and prevent injury to birds.

ii) Gas delivery pipes or lancets should be positioned appropriately such that birds are not hit directly by very cold gas delivered at high pressures. It may be necessary to exclude birds from the

area in front of the delivery pipes, for a distance of about 20 meters, by partitioning the house with nets, wire mesh or similarly perforated materials.

iii) The house should be gradually filled with CO_2 so that all birds are exposed to a concentration of >40% until they are dead; a vaporiser may be required to prevent freezing.

Annex XIII (contd)

iv) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.

b) Advantages

i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.

ii) CO_2 is readily available.

iii) Gradual raising of CO_2 concentration minimises the aversiveness of the induction of unconsciousness.

c) Disadvantages

i) It is difficult to determine volume of gas required to achieve adequate concentrations of $CO_2$2 in some poultry houses.

ii) It is difficult to verify *death* while the birds are in the poultry house.

The extremely low temperature of liquid CO_2 entering the house and formation of solid CO_2 (dry ice) may cause concern for bird *welfare*.

d) Conclusion

Method 3~~2~~ is suitable for use in poultry in closed-environment sheds. This method could be developed for killing pigs. However, CO_2 is likely to cause a period of distress in the birds before they lose consciousness.

Article 7.6.13.

Nitrogen and/or inert gas mixed with CO2

1. Introduction

CO2 may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and *death* when the oxygen concentration by volume is <2%. Various mixtures of CO2 and nitrogen or an inert gas can be administered to kill birds using Methods 1 and ~~3~~2 described under 7.6.12. Whole house gassing with mixtures of CO2 and nitrogen, or an inert gas, has not been tested owing to the complex issues presented by mixing gases in large quantities. Such mixtures however do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO2 and the respiratory distress occurring during the induction phase, are important *animal welfare* considerations.

EU comment

The EU would like to reiterate its previous comment.

In point 1 of Article 7.6.13, the EU suggests replacing the end of the first sentence ending by "by volume is <2%" by "by volume is ≤5%. However, this oxygen concentration by volume should be <2% in the case of ducks and geese".

Other references to the limit of 2% should be amended accordingly.

Justification

Both research and practical experience support the use of 5% for chickens' and 2% for ducks and geese. This is of practical importance as it requires significantly more gas to reach a

concentration of oxygen lower than 2 % and takes significantly longer which would result in an important reduction in speed of kill and increase of cost of kill without any welfare benefit.

Raj et al 2008 Development of a humane containerised gassing systems 2008 World

Poultry Science 2008 64 227 244

Susceptibility of Duck and Turkey to Severe Hypercapnic Hypoxia M. A. Gerritzen,* E.

Lambooij,* H. G. M. Reimert,* B. M. Spruijt,† and J. A. Stegeman* 2006 Poultry

Science 85:1055–1061

Pigs and poultry appear not to find low concentrations of CO2 strongly aversive, and a mixture of nitrogen or argon with <30% CO2 by volume and <2% O2 by volume can be used for *killing* poultry, neonatal sheep, goats and pigs.

EU comment

The EU would like to reiterate its previous comment.

In the above paragraph, the EU suggests modifying the last part of the sentence by the following "and <u>2% to 5%</u> by volume can be used for killing neonatal sheep, goats and pigs <u>and all poultry except ducks and geese which require <2% oxygen by volume levels</u>"

Justification

See previous comment

2. <u>Method 1</u>

The *animals* are placed in a gas-filled *container* or apparatus.

a) Requirements for effective use

i) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O2 and CO2 concentrations accurately measured during the *killing* procedure.

ii) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

iii) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2% O2), and held in this atmosphere until *death* is confirmed.

iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.

b) Advantages

i) Low concentrations of CO2 cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

ii) The volume of gas required can be readily calculated.

iii) As the units are operated outdoors, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.

iv) Metal containers can be readily cleansed and disinfected.

v) Mixtures containing up to 20% carbon dioxide in argon are readily available as welding gas cylinders.

c) Disadvantages

i) A properly designed *container* or apparatus is needed.

ii) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.

EU comment

We suggest adding after (2) (c) (ii) the sentence already used for other methods *"However cessation of vocalisations and convulsing wing flapping sounds can be used to determine the onset of unconsciousness that will in due time lead to death* ".

iii) There is no immediate loss of consciousness.

iv) Exposure times required to kill are considerable.

v) The risk of suffocation due to overcrowding.

d) Conclusion

The method is suitable for poultry, and for neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a *container* and gas is introduced into the *container* (refer to Figures under Article 7.6.12.). As shown in the example below, each containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate poultry transport crates or a module. The *container* or chamber is fitted with gas lines and diffusers, with silencers, which in turn are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top of the unit to permit displaced air to escape when filling the *container* with gas.

Procedures involved in the operation of CGU includes (a) position the *container* on a level, solid, open ground; (b) connect gas cylinder to the *container* (c) load a module of birds into the *container*, (d) shut and secure the door, (e) deliver the gas to the point where less than 2% by volume of oxygen is found at the top of the *container*, (f) allow time for the birds to become unconscious and die, (g) open the door and allow the gas to be dispersed in air, (h) remove the module, (i) check each drawer for survivors; (j) humanely kill survivors, if any; and (k) dispose carcasses appropriately.

a) Requirements for effective use of containerised gassing units (CGU)

i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.

ii) The crates or module of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas mixture.

iii) Ensure the *container* door is locked and administer the gas mixture until <2% residual oxygen is achieved at the top of the crates.

iv) An appropriate gas meter should be used to ensure a concentration of oxygen <2% is achieved and maintained until it can be confirmed that the birds have been killed.

v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window, which allows direct observation of birds during killing, cessation of

vocalisation and wing flapping sounds can be observed by standing close to the *container* and used to determine the onset of *death* in birds. Remove the crates or modules from the *container* and leave them in the open air.

vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing movements indicate *death.*

vii) Any survivors should be humanely killed.

viii) Ducks and geese do not appear to be resilient to the effects of a mixture of 20% carbon dioxide and 80% nitrogen or argon.

b) Advantages

i) The gas mixture is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.

ii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.

iii) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.

iv) Mixtures containing up to 20% carbon dioxide in argon are readily available as welding gas cylinders.

v) Birds are exposed to gas in a more uniform manner and they do not smother each other when compared with Method 1.

vi) Two CGU can be operated in tandem and throughputs of up to 4,000 chickens per hour are possible.

vii) The volume of gas required can be readily calculated.

viii) As the units are operated outdoor the gas is dispersed quickly at the end of each cycle by opening the door, improving operators' health and safety.

ix) The system uses skilled catching teams and equipment in daily use by the industry.

x) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and a fork lift. However, such equipment and suitable outdoor areas with a hard surface are usually available.

ii) The main limiting factors are speed of catching birds and availability of gas mixtures.

iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping can be used to determine the onset of *death.*

iv) CGU could be used to kill poultry on small to medium farms, e.g. up to 25 thousand birds on a single farm.

d) Conclusion

i) Method 2 is suitable for use in poultry and in neonatal sheep, goats and pigs.

ii) Method 2 is suitable for use in poultry in a wide range of poultry systems providing that these have access to *vehicles* to carry *containers* and equipment.

iii) *Animals* should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the gas mixture. A residual oxygen concentration of less than 2% should be achieved and maintained and birds should be held in this atmosphere until *death* is confirmed.

Article 7.6.14.

Nitrogen and/or inert gases

1. Introduction

This method involves the introduction of *animals* into a *container* or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and *death* from hypoxia.

Research has shown that hypoxia is not aversive to pigs and poultry, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O2 concentration accurately measured.

b) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

c) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2% O2), and held in this atmosphere until *death* is confirmed.

d) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

e) *Containers* or apparatus should not be overcrowded, and measures are needed to avoid *animals* suffocating by climbing on top of each other.

3. Advantages

Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to *animals*.

4. Disadvantages

a) A properly designed *container* or apparatus is needed.

b) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

Article 7.6.15.

Lethal injection

1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and *death*. In practice, barbiturates in combination with other drugs are commonly used.

Annex XIII (contd)

2. Requirements for effective use

   a) Doses and routes of administration that cause rapid loss of consciousness followed by *death* should be used.

   b) Prior sedation may be necessary for some *animals*.

   c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.

   d) *Animals* should be restrained to allow effective administration.

   e) *Animals* should be monitored to ensure the absence of brain stem reflexes.

3. Advantages

   a) The method can be used in all species.

   b) *Death* can be induced smoothly.

4. Disadvantages

   a) *Restraint* and/or sedation may be necessary prior to injection.

   b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious *animals*.

   c) Legal requirements and skill/training required may restrict use to veterinarians.

   d) Contaminated carcasses may present a risk to other wild or domestic *animals*.

5. Conclusion

   The method is suitable for *killing* small numbers of cattle, sheep, goats, pigs and poultry.

Article 7.6.16.

Addition of anaesthetics to feed or water

1. Introduction

   An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation.

2. Requirements for effective use

   a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.

   b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.

   c) Should be followed by *killing* (see Article 7.6.17.) if birds are anaesthetised only.

3. Advantages

   a) Handling is not required until birds are anaesthetised.

   b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages

a) Non-target *animals* may accidentally access the medicated feed or water when provided in an open environment.

b) Dose taken is unable to be regulated and variable results may be obtained.

c) *Animals* may reject adulterated feed or water due to illness or adverse flavour.

d) The method may need to be followed by *killing*.

e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

5. Conclusion

The method is suitable for *killing* large numbers of poultry in houses. However, a back-up method should be available to kill birds that are anaesthetized but not killed.

Article 7.6.17.

Cervical dislocation and decapitation

1. Cervical dislocation (manual and mechanical)

a) Introduction

Unconscious poultry may be killed by either manual cervical dislocation (stretching the neck). This method results in *death* from cerebral anoxia due to cessation of breathing and/or blood supply to the brain.

EU Comment

In point 1. a) of Art 7.6.17, the words "*or mechanical*" should be added after the word "*manual*".

Justification

To clarify the word "*either*".

When the number of birds to be killed is small, and other methods of *killing* are not available, conscious birds of less than 3 kilograms may be killed using cervical dislocation in such a way that the blood vessels of the neck are severed and *death* is instantaneous.

b) Requirements for effective use

i) *Killing* should be performed either by manually or mechanically stretching the neck to sever the spinal cord or by using mechanical pliers to crush the cervical vertebrae with consequent major damage to the spinal cord.

EU Comment

In point 1. b.i) of Art 7.6.17, the text "or by using mechanical pliers to crush the cervical vertebrae" should be deleted.

Justification

Paper from Gregory, N.G. and Wotton, S.B. (1990). "Comparison of neck dislocation and percussion of the head on visual evoked responses in the chicken's brain." Veterinary Record 126: 570-572:

In this paper the proportion of birds that failed to show changes to the visual evoked response (sign of electrical brain activity) was 25% in birds killed by neck dislocation by stretching and 69% in birds killed with the Semark pliers. This information very strongly suggests that the Semark pliers are not a humane method of killing. It also explains further how crushing does not affect the carotid arteries diameter, as occurs in stretching, leading to a continued blood flow to the brain. Additionally the paper notes that the pliers not always sever the spinal cord, so it is possible that they may not even consistently kill a bird by asphyxia.

ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.

iii) Birds should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

i) It is a non-invasive *killing* method.

ii) It can be performed manually on small birds.

d) Disadvantages

EU comment

The EU would like to reiterate its previous comment.

We suggest adding the following disadvantage under point 1. d) of Article 7.6.17

"i) animals may not always been stunned."

i) Operator fatigue.

ii) The method is more difficult in larger birds.

iii) Requires trained personnel to perform humanely.

iv) Human health and safety concerns due to handling of the birds.

v) Additional stress to the *animals* from handling.

2. Decapitation

a) Introduction

Decapitation results in *death* by cerebral ischaemia using a guillotine or knife.

b) Requirements for effective use

The required equipment should be kept in good working order.

c) Advantages

The technique is effective and does not require monitoring.

d) Disadvantages

i) The working area is contaminated with body fluids, which increases biosecurity risks.

ii) Pain if consciousness is not lost immediately.

Article 7.6.18.

Pithing and bleeding

1. Pithing

a) Introduction

Pithing is a method of *killing animals* which have been stunned by a penetrating captive bolt, without immediate *death*. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

b) Requirements for effective use

i) Pithing cane or rod is required.

ii) An access to the head of the *animal* and to the brain through the skull is required.

iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing immediate *death*.

d) Disadvantages

i) A delayed and/or ineffective pithing due to convulsions may occur.

ii) The working area is contaminated with body fluids, which increases biosecurity risks.

2. Bleeding

a) Introduction

Bleeding is a method of *killing animals* through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and *death*.

b) Requirements for effective use

i) A sharp knife is required.

ii) An access to the neck or chest of the *animal* is required.

iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing *death* after an effective *stunning* method which does not permit pithing.

d) Disadvantages

i) A delayed and/or ineffective bleeding due to convulsions may occur.

ii) The working area is contaminated with body fluids, which increases biosecurity risks.

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— text deleted

The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.

CHAPTER 7.7.

STRAY DOG POPULATION CONTROL

EU comments

The EU notes with satisfaction that some previous EU comments were taken into account by the OIE. The EU also supports the amendments proposed by the Code Commission in this latest version.

However, the EU strongly encourages OIE to consider a previous specific comment which is reiterated within the text at article 7.7.4, given its importance to the EU.

Preamble: The scope of these recommendations is to deal with stray and feral dogs, which pose serious human health, animal health and welfare problems and have a socio-economic, environmental, political and religious impact in many countries. Whilst acknowledging human health is a priority including the prevention of zoonotic diseases notably rabies (Chapter 8.10.), dog population management is an integral part of rabies control programmes, the OIE recognises the importance of controlling dog populations without causing unnecessary or avoidable animal suffering. *Veterinary Services* should play a lead role in preventing zoonotic diseases and ensuring *animal welfare* and should be involved in dog population control, coordinating their activities with other competent public institutions and/or agencies.

Article 7.7.1.

Guiding principles

The following recommendations are based on those laid down in Chapter 7.1. Some additional principles are relevant to these recommendations:

1. The promotion of responsible dog ownership can significantly reduce the numbers of stray dogs and the incidence of zoonotic diseases.
2. Because dog ecology is linked with human activities, control of dog populations has to be accompanied by changes in human behaviour to be effective.

Article 7.7.2.

Definitions

Carrying capacity*:* means the upper limit of the dog population density that could be supported by the habitat based on the availability of resources (food, water, shelter), and human acceptance.

Dog population control programme*:* means a programme with the aim of reducing a stray dog population to a particular level and/or maintaining it at that level and/or managing it in order to meet a predetermined objective (see Article 7.7.3.).

~~***Euthanasia:*** means the act of inducing *death* in a humane manner.~~

Owned dog: means a dog with a person that claims responsibility.

EU comment

The EU would like to modify the definition above as follow:

"means a dog for which a person claims responsibility".

Justification

Linguistic clarification.

Person*:* this can include more than one individual, and could comprise family/household members or an organisation.

Responsible dog ownership*:* means the situation whereby a person (as defined above) accepts and commits to perform various duties according to the legislation in place and focused on the satisfaction of the behavioural, environmental and physical needs of a dog and to the prevention of risks (aggression, *disease* transmission or injuries) that the dog may pose to the community, other *animals* or the environment.

Stray dog*:* means any dog not under direct control by a person or not prevented from roaming. Types of stray dog:

1. free-roaming owned dog not under direct control or restriction at a particular time;
2. free-roaming dog with no owner;
3. feral dog: domestic dog that has reverted to the wild state and is no longer directly dependent upon humans for successful reproduction.

Article 7.7.3.

Dog population control programme objectives

The objectives of a programme to control the dog population may include the following:

1. improve health and welfare of owned and stray dog population;
2. reduce numbers of stray dogs to an acceptable level;
3. promote responsible ownership;
4. assist in the creation and maintenance of a rabies immune or rabies free dog population;
5. reduce the *risk* of zoonotic diseases other than rabies;
6. manage other *risks* to human health (e.g. parasites);
7. prevent harm to the environment and other *animals*;
8. prevent illegal trade and trafficking.

Article 7.7.4.

Responsibilities and competencies

1. Veterinary Authority

   The *Veterinary Authority* is responsible for the implementation of animal health and *animal welfare* legislation, in coordination with other competent government agencies and institutions. Control of endemic zoonotic diseases such as rabies and parasitic *infections* (e.g. *Echinococcus* spp.) would require technical advice from the *Veterinary Authority*, as animal health and some aspects of public health are within this Authority's competence but organising and/or supervising dog control schemes can be the responsibility of non-governmental organisations and governmental agencies other than the *Veterinary Authority*.

EU comment

The EU would like to reiterate its previous comment given its importance and encourages the OIE to consider it. Moreover the EU would wish to receive explanation why the comment is not taken on board.

The title of Point 1 of Art 7.7.4 "*Veterinary Authority*" should be replaced by "*Veterinary Authority* and *other Competent Authority*".

Furthermore, the following text should be inserted as second sentence of the paragraph in Point 1 "In some cases animal welfare is under the responsibility of other *Competent Authority* than the *Veterinary Authority*".

Justification

As defined in the Glossary of the Terrestrial Code, "Competent Authority" includes the Veterinary Authority as well as other Governmental Authority of an OIE Member having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures.

2. Other government agencies

The responsibilities of other government agencies will depend on the risk being managed and the objective/nature of the dog population control measures employed.

The ministry or other agency responsible for public health would normally play a leadership role and may have legislative authority in dealing with zoonotic diseases. Control of stray dogs with regard to other human health risks (e.g. stray dogs on roads; dog attacks within communities) may fall within the responsibility of the public health agency but is more likely to be the responsibility of the local government authorities or other agencies for public safety/security operating at the state/provincial or municipal level.

Environment protection agencies may take responsibility for control problems associated with stray dogs when they present a hazard to the environment (e.g. control of feral dogs in national parks; prevention of dog attacks on wildlife or transmission of *diseases* to wildlife) or where a lack of environmental controls is giving rise to stray dog populations that threaten human health or access to amenities. For example, environmental protection agencies may regulate and enforce measures to prevent dogs from accessing waste or human sewage.

3. Private sector veterinarians

The private sector *veterinarian* is responsible for providing advice to dog owners or handlers consulting the *veterinarian* for advice or treatment of a dog. The private sector *veterinarian* can play an important role in *disease surveillance* because he/she might be the first to see a dog suffering from a *notifiable disease* such as rabies. It is necessary that the private sector *veterinarian* follow the procedure established by the *Veterinary Authority* for responding to and reporting a suspected rabies case or a dog that is suffering from any other *notifiable disease*. Private sector *veterinarians* also play an important role (often in liaison with the police and/or local authorities) in dealing with cases of neglect that can lead to problems with stray and mismanaged dogs.

The private *veterinarian* has competence and will normally be involved in dog health programmes and population control measures, including health testing, vaccination, identification, kennelling during the absence of the owner, sterilisation and euthanasia. Two-way communication between the private sector *veterinarian* and *Veterinary Authority*, often via the medium of a veterinary professional organisation, is very important and the *Veterinary Authority* is responsible for setting up appropriate mechanisms for this action.

4. Non governmental organisations

Non governmental organisations (NGOs) are potentially important partners of the *Veterinary Services* in contributing to public awareness and understanding and helping to obtain resources to contribute in a practical way to the design and successful implementation of dog control programmes. NGOs can supply local knowledge on dog populations and features of ownership, as well as expertise in handling and kennelling dogs and the implementation of sterilisation programmes. NGOs can also contribute, together with *veterinarians* and the authorities in educating the public in responsible dog ownership.

5. Local government authorities

Local government authorities are responsible for many services and programmes that relate to health, safety and public good within their jurisdiction. In many countries the legislative framework gives authority to local government agencies in regard to aspects of public health, environmental health/hygiene and inspection/compliance activities.

In many countries local government agencies are responsible for the development and enforcement of legislation relating to dog ownership (e.g. registration, microchipping, vaccination, leash laws, abandonment), the control of stray dogs (e.g. dog catching and shelters) and the alleviation of the problems stray dogs cause in their jurisdiction. This would normally be done with advice from a higher level (national or state/provincial) authority with specialised expertise in regard to public health and animal health. Collaboration with the private sector *veterinarians* (e.g. in programmes to sterilise and vaccinate stray dogs) and NGOs is a common feature of dog control programmes. Regardless of the legislative basis, it is essential to have the co-operation of local government authorities in the control of stray dogs.

6. Dog owners

When a person takes on the ownership of a dog, there should be an immediate acceptance of responsibility for that dog, and for any offspring it may produce, for the duration of its life or until a subsequent owner is found. The owner should ensure that the welfare of the dog, including behavioural needs, are respected and the dog is protected, as far as possible, from infectious *diseases* (e.g. through vaccination and parasite control) and from unwanted reproduction (e.g. through contraception or sterilisation). Owners should ensure that the dog's ownership is clearly identified (preferably with permanent identification such as a tattoo or microchip) and, where required by legislation, registered on a centralised database. All reasonable steps should be taken to ensure that the dog does not roam out of control in a manner that would pose a problem to the community and/or the environment.

Article 7.7.5.

In the development of a dog population control programme it is recommended that the authorities establish an advisory group, which should include *veterinarians*, experts in dog ecology, dog behaviour and zoonotic diseases, and representatives of relevant stakeholders (local authorities, human health services/authorities, environmental control services/authorities, NGOs and the public). The main purpose of this advisory group would be to analyse and quantify the problem, identify the causes, obtain public opinion on dogs and propose the most effective approaches to use in the short and long term.

Important considerations are as follows:

1. Identifying the sources of stray dogs

   a) owned dogs that roam freely;

   b) dogs that have been abandoned by their owner, including puppies resulting from uncontrolled breeding of owned dogs;

   c) unowned dogs that reproduce successfully.

2. Estimating the existing number, distribution and ecology

Practical tools that are available include registers of dogs, population estimates, and surveys of dogs, owners, dog shelters and *veterinarians*. The important factors relevant to the dog carrying capacity of the environment include food, shelter, water and human attitudes and behaviour.

A methodology could be established to make an estimate of the total dog population. An overview of appropriate methodologies may be found in Article 7.7.8. The same methodology could be used at appropriate intervals to assess population trends.

3. Regulatory framework

A regulatory framework that would help authorities establish successful dog control programmes could include the following key elements:

a) registration and identification of dogs and licensing of dog breeders;

b) vaccination against rabies and other preventive measures against zoonotic disease, as appropriate;

c) veterinary procedures (e.g. surgical procedures);

d) control of dog movement (national and international);

e) control of dangerous dogs;

f) regulations on the breeding and sale of dogs;

g) environmental controls (e.g. *abattoirs*, rubbish dumps, dead stock facilities);

h) regulations for dog shelters;

i) *animal welfare* obligations of owners and authorities.

4. Resources available to authorities

a) Human resources;

b) financial resources;

c) technical tools;

d) infrastructure;

e) cooperative activities;

f) public-private-NGO partnerships;

g) central-state or province-local partnerships.

Article 7.7.6.

Control measures

The following control measures could be implemented according to the national context and local circumstances. Measures may be used in combination. Euthanasia of dogs, used alone, is not an effective control measure. If used, it should be done humanely (see point 11 of Article 7.7.6.) and in combination with other measures to achieve effective long term control. It is also important that authorities gain an understanding of people's attitudes towards dog ownership so that they can develop a cooperative approach to the control of dog populations.

1. Education and legislation for responsible ownership

Encouraging dog owners to be more responsible will reduce the number of dogs allowed to roam, improve the health and welfare of dogs, and minimise the risk that dogs pose to the community. The

promotion of responsible dog ownership through legislation and education is a necessary part of a dog population control programme. Collaboration with local government authorities, *animal welfare* NGOs, kennel clubs, private *veterinarians* and veterinary organisations will assist *Veterinary Authorities* in establishing and maintaining programmes.

Education on responsible dog ownership (for the currently owned dog and any offspring it produces) should address the following elements:

a) the importance of proper selection for behaviour and care to ensure the welfare of the dog and any offspring; the latter may include preparing the dog to cope with its environment through attention to socialisation and training;

b) registration and identification of dogs (see point 2 of Article 7.7.6.);

c) *disease* prevention, in particular zoonotic disease, e.g. through regular vaccination in rabies endemic areas;

d) preventing negative impacts of dogs on the community, via pollution (e.g. faeces and noise), risks to human health through biting or traffic accidents and risks to other dogs, wildlife, livestock and other companion animal species;

e) control of dog reproduction.

In order to achieve a shift towards responsible ownership, a combination of legislation, public awareness, education, and promotion of these elements will be required. It may also be necessary to improve access to resources supporting responsible ownership, such as veterinary care, identification and registration services and measures for control of zoonotic diseases.

2. Registration and identification of dogs (licensing)

A core component of dog population control by the *Competent Authorities* is the registration and identification of owned dogs. This may include granting licences to owners and breeders. Registration and identification may be emphasized as part of responsible dog ownership and are often linked to animal health programmes, for example, mandatory rabies vaccination and traceability.

Registration of *animals* in a centralised database can be used to support the enforcement of legislation and the reuniting of lost *animals* with owners. The control of dog reproduction by sterilisation can be encouraged through financial incentives presented by differential licensing fees.

3. Reproductive control

Controlling reproduction in dogs prevents the birth of unwanted puppies and can help address the balance between demand for dogs and the size of the population. It is advisable to focus efforts to control reproduction on those individuals or groups in the dog population identified as the most productive and the most likely to be the sources of unwanted and stray dogs, to ensure best use of resources. Methods of controlling reproduction will require direct veterinary input to individual *animals*. Involvement of both private and public veterinary sectors may be required to meet demand for services. Subsidisation of sterilisation programmes by government or other organisations may be considered to encourage uptake. The control of reproduction is essentially the responsibility of owners and can be incorporated into education on responsible ownership (see point 1 of Article 7.7.6.). Methods for controlling reproduction in dogs include:

a) surgical sterilisation;

b) chemical sterilisation;

c) chemical contraception;

d) separation of female dogs during oestrus from unsterilised males.

Surgical sterilisation should be carried out by a *veterinarian* and include appropriate anaesthesia and pain management.

Any chemicals or drugs used in controlling reproduction should be shown to have appropriate safety, quality and efficacy for the function required and used according to the manufacturer's and *Competent Authority*'s regulations. In the case of chemical sterilants and contraceptives, research and field trials may need to be completed before use.

4. Removal and handling

The *Competent Authority* should collect dogs that are not under direct supervision and verify their ownership. Capture, transport, and holding of the dogs should be done humanely. The *Competent Authority* should develop and implement appropriate legislation and training to regulate these activities. Capture should be achieved with the minimum force required and equipment should be used that supports humane handling. Uncovered wire loops should not be used for capture.

5. Capture and return, rehoming or release

Competent Authorities have the responsibility to develop minimum standards for the housing (physical facilities) and care of these dogs. There should be provision for holding the dogs for a reasonable period of time to allow for reunion with the owner and, as appropriate, for rabies observation.

a) Minimum standards for housing should include the following provisions:

   i) site selection: access to drainage, water and electricity are essential and environmental factors such as noise and pollution should be taken into account;

   ii) kennel size, design and occupancy taking exercise into account;

   iii) *disease* control measures including isolation and quarantine facilities.

b) Management should address:

   i) adequate fresh water and nutritious food;

   ii) regular hygiene and cleaning;

   iii) routine inspection of the dogs;

   iv) monitoring of health and provision of required veterinary treatments;

   v) policies and procedures for rehoming (adoption), sterilisation and euthanasia;

   vi) training of staff in safe and appropriate handling of dogs;

   viii) record keeping and reporting to authorities.

Dogs that are removed from a community may be reunited with the owner or offered to new owners for rehoming. This provides an opportunity to promote responsible ownership and good animal health care (including rabies vaccination). Prior to rehoming, authorities may consider sterilisation of dogs as a population control measure. The suitability of new owners to adopt dogs should be assessed and owners matched with available *animals*. The effectiveness of rehoming may be limited due to the suitability and number of dogs.

Dogs that are removed from a community may in some cases be provided with health care (including rabies vaccination), sterilised, and released to their local community at or near the place of capture. This method is more likely to be accepted in the situation where the presence of stray dogs is considered to be inevitable and is well tolerated by the local community.

Annex XIII (contd)

This method is not applicable in all situations and may be illegal in countries or regions where legislation prohibits the abandonment of dogs. Problems caused by dogs, such as noise, faecal pollution, bite injuries and traffic accidents, would not be alleviated as dogs are returned to the local community and their movements are not restricted. If the local community has owned dogs, and sterilised dogs are released, consideration should be given to the risk that this could encourage abandonment of unwanted dogs. In the situation where many dogs are owned, a population control programme that focuses on neutering and responsible ownership may be more appropriate.

It is recommended that before adopting this approach, a cost-benefit analysis is conducted. Factors such as the monetary costs, impact on culture of ownership and public safety should be assessed as well as the benefits for *disease* control and *animal welfare* as well as any societal benefits.

c) If this method is adopted, the following factors should be addressed:

i) raising awareness of the programme within the local community to ensure understanding and support;

ii) use of humane methods for catching, transporting and holding dogs;

iii) correct surgical technique, anaesthesia and analgesia, followed by post-operative care;

iv) *disease* control may include blanket vaccination (e.g. rabies) and treatments and testing for *diseases* (e.g. leishmaniasis) followed, as appropriate by treatment or euthanasia of the dog;

v) behavioural observation may be used to assess if dogs are suitable for release; if not suitable for release or rehoming, euthanasia should be considered;

vi) permanent marking (e.g. tattoo or microchip) to indicate that the *animal* has been sterilised; individual identification also allows for tracking of vaccination status and treatment history and identification of a level of 'ownership' by the organisation/authority responsible for carrying out this intervention; a visible identification (e.g. collar) may also be used to prevent unnecessary recapture;

vii) the dog should be returned to a place that is as near as possible to the place of capture;

viii) the welfare of dogs after release should be monitored and action taken if required.

Dogs that are removed from a community may be too numerous or may be unsuitable for any rehoming scheme. If euthanasia of these unwanted animals is the only option, the procedure should be conducted in accordance with the regulations of the Competent Authority (see point 11 of Article 7.7.6.).

6. Environmental controls

Steps should be taken to exclude dogs from sources of food (e.g. rubbish dumps and *abattoirs*, and installing animal-proof rubbish containers).

This should be linked to a reduction in the dog population by other methods, to avoid *animal welfare* problems.

7. Control of dog movement – international (export/import)

Chapter 8.10. provides recommendations on the international movement of dogs, with respect to provision for ~~between~~ rabies ~~free countries and countries considered to be infected with rabies~~.

8. Control of dog movements – within country (e.g. leash laws, roaming restrictions)

Measures for the control of dog movement in a country are generally invoked for the following reasons:

a) for rabies control when the *disease* is present in a country;

b) for public safety reasons;

c) for the safety of 'owned dogs' in an area or locality when a stray dog control programme is in place;

d) to protect wildlife and livestock.

It is necessary to have a regulatory framework and a national or local infrastructure comprising organisation, administration, staff and resources to encourage the finders of stray dogs to report to the *Competent Authority*.

9. Regulation of commercial dog dealers

Dog breeders and dealers should be encouraged to form or join an appropriate association. Such associations should encourage a commitment to the raising and selling of physically and psychologically healthy dogs, as unhealthy dogs may be more likely to be abandoned to become part of the stray population. They should encourage breeders and dealers to provide advice on proper care to all new owners of dogs. Regulations covering commercial dog breeders and dealers should include specific requirements for accommodation, provision of suitable food, drink and bedding, adequate exercise, veterinary care and disease control and may require breeders and dealers to allow regular inspection, including veterinary inspection.

10. Reduction in dog bite incidence

The most effective means of reducing prevalence of dog bites are education and placing responsibility on the owner. Dog owners should be educated in principles of responsible dog ownership as described in point 1 of Article 7.7.6.) Legal mechanisms that enable the Competent Authorities to impose penalties or otherwise deal with irresponsible owners are necessary. Mandatory registration and identification schemes will facilitate the effective application of such mechanisms. Young children are the group at highest risk for dog bites. Public education programmes focussed on appropriate dog-directed behaviour have been demonstrated to be effective in reducing dog bite prevalence and these programmes should be encouraged. Authorities should seek advice from dog behaviour experts in developing dog safety education programmes.

11. Euthanasia

When euthanasia is practised, the general principles in the Terrestrial Code should be followed, with the emphasis on using the most practical, rapid and humane methods and ensuring operator safety. Regardless of the method used, it is important to minimise distress, anxiety and pain by ensuring that operators are appropriately trained.

Table 1 shows a summary analysis of methods for the euthanasia of dogs.

Comments on methods for the euthanasia of dogs:

a) Restraint

When a dog needs to be restrained for any procedure, including euthanasia, this should always be done with full regard for operator security and *animal welfare*. Some euthanasia methods should be used in association with sedation or anaesthesia in order to be considered humane.

b) Special equipment

When special equipment is needed to perform euthanasia (e.g. gas chamber), the system should be designed for the purpose and regularly maintained in order to achieve operator security and *animal welfare.*

c) The following methods, procedures and practices are unacceptable on *animal welfare* grounds:

i) Chemical methods:

- Embutramide +Mebezonium +Tetracaine without sedation or by other than IV injection
- Chloral hydrate
- Nitrous oxide: may be used with other inhalants to speed the onset of anaesthesia, but alone it does not induce anaesthesia in dogs
- Ether
- Chloroform
- Cyanide
- Strychnine
- Neuromuscular blocking agents (nicotine, magnesium sulphate, potassium chloride, all curariform agents): when used alone, respiratory arrest occurs before loss of consciousness, so the dog may perceive pain
- Formalin
- Household products and solvents.

ii) Mechanical methods:

- Air embolism on conscious *animal*
- Burning
- Exsanguination of conscious animal
- Decompression: expansion of gas trapped in body cavities may be very painful
- Drowning
- Hypothermia, rapid freezing
- Stunning: stunning is not a euthanasia method, it should always be followed by a method which ensures death
- Kill-trapping
- Electrocution of conscious *animal*.

Because neonatal *animals* and adults with impaired breathing or low blood pressure are resistant to hypoxia, methods that depend upon achieving a hypoxic state (e.g. CO2, CO, N2, Ar) should not be used. These methods should not be used in *animals* aged less than 2 months, except to produce loss of consciousness and should be followed by another method to cause *death*. Concussion and cervical dislocation may be used in very small neonatal dogs and only in cases of emergency.

Operators should be well trained in the use of physical techniques to ensure that they are correctly and humanely carried out. The dog should be exsanguinated immediately after concussion or cervical dislocation.

d) Confirmation of death

For all methods of euthanasia used, *death* should be confirmed before *animals* are disposed of or left unattended. If an *animal* is not dead, another method of euthanasia should be performed.

e) Carcass disposal

Carcasses should be disposed of in a manner that complies with legislation. Attention should be paid to the risk of residues occurring in the carcass. Incineration is generally the safest way of carcass disposal.

EU Comment

The EU wishes to reintroduce the following title for the table in point 11.e) of Art 7.7.6

"*Table 1 Summary analysis of methods used for euthanasia of dogs*"

Justification:

Clarity

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Chemical via infection	Barbiturates	Correct restraint is needed. IP is slow and may be irritant. IC injection is a painful procedure.	Recommend to use IV injection. When using IP injection, the solution may be diluted or local anaesthetic agent used in conjunction. IC should only be performed on unconscious animal and by skilled operator.	Correct restraint is needed. Administered under veterinary supervision and requires trained personnel.	Speed of action generally depends on the dose, concentration, route and rate of injection. Barbiturates induce euthanasia smoothly, with minimal discomfort to the animal. Barbiturates are less expensive than many other euthanasia agents.	These drugs persist in the carcass and may cause sedation or death in animals that consume the cadaver.
	Embutramide +Mebezonium +Tetracaine	Muscle paralysis may occur before lost of consciousness if injection given rapidly.	Use slow IV injection with sedation to permit slow rate of injection.	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Quite low cost.	Unavailable/ unlicensed in some countries.
	Anaesthetic agent overdose (thiopentone or propofenol)	Underdosing may lead to recovery.	IV injection of a sufficient dose.	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Generally quick action and minimal discomfort to animal.	Large volume required (cost implications).

Annex XIII (contd)

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
	Potassium chloride (KCl)	K+ is cardiotoxic and very painful if used without anaesthetic agent.	Only use on anaesthetised animals, IV injection.	Requires trained personnel.	Readily available without veterinary control.	Prior need for anaesthetic (cost and availability implications).
Mechanical	Free bullet	Can be inhumane if shot is inaccurate and dog is only wounded; dog may also escape.	Skilled operator essential.	Risk of injury to operators and spectators.	Not necessary to handle or capture dog.	Brain tissue may be unavailable for rabies diagnosis. Risk of injury to bystanders. Legal constraints on use of firearms.
Mechanical (contd)	Penetrating captive bolt followed by pithing where necessary to ensure death	Can be inhumane if shot is inaccurate and dog is only wounded.	Skilled operator essential.	Animal should be restrained. Skilled operator essential.	No risk to operator (see free bullet) unless risk of dog infected with rabies, due to potential contact with brain tissue.	Brain tissue may be unavailable for rabies diagnosis. Legal constraints on use of firearms. May raise aesthetic objections.
	Exsanguination	Onset of hypovolaemia may cause dog to become anxious.	Only use on unconscious animal.	Danger to operator through use of sharp instrument.	Material requirements minimal.	~~Should be done on unconscious animal.~~ Need to render animal unconscious. Aesthetically objectionable.
Gaseous	Carbon monoxide (CO)	Inadequate concentration of CO is not lethal and can cause suffering. Signs of distress (convulsions, vocalization and agitation) may occur.	Compressed CO in cylinders should be used to achieve and maintain adequate concentration, which should be monitored. Note: fumes from gasoline engines are an irritant and this source of CO is not recommended.	Very hazardous for operator - gas is odourless and causes toxicity at both acute high levels and chronic low levels.	Dog dies quite rapidly if concentration of 4 to 6% used. No odour (therefore no aversive effect). Gas is not flammable or explosive except at concentration greater than 10%.	
	Carbon dioxide (CO_2)	Gas is aversive. Inadequate concentration of CO_2 is not lethal and can cause suffering. CO_2 is heavier than air, so when incomplete filling of the chamber occurs, dogs may raise their head and avoid exposure. Few studies on adequate concentration and animal welfare.	Compressed CO_2 gas chamber is the only acceptable method because the concentration can be monitored and regulated.	Minimal hazard to operator when properly designed equipment used.	Gas is not flammable or explosive and causes quite rapid anaesthesia when correct concentrations used. Low cost. Readily available as compressed gas.	Unconscious-ness can occur in minutes, but death may take some time. Likelihood of suffering before unconscious-ness.

Annex XIII (contd)

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Gaseous (contd)	Inert gas (nitrogen, N2 argon, Ar)	Loss of consciousness is preceded by hypoxemia and ventilatory stimulation, which may be distressing to the dog. Re-establishing a low concentration of O2 (i.e. greater than or equal to 6%) in the chamber before death will allow immediate recovery.	Concentration above 98% should be achieved rapidly and maintained. Properly designed equipment should be used.	Minimal hazard to operator when properly designed equipment used.	Gas is not flammable or explosive and is odourless. Readily available as compressed gas.	High cost. Little data on animal welfare implications in dogs.
	Anaesthetic gas overdose (halothane or enflurane)	Animal may struggle and become anxious during induction. Vapours may be irritating and can induce excitement.	Supplementa-tion with air or O2 required to avoid hypoxemia during induction phase.	Some gases may be hazardous, especially for pregnant women. General recommen-dation: avoid human exposure to greater than or equal to 2 ppm to avoid narcosis.	Gas is not flammable or explosive. Valuable for use with small animals (<7 kgs) and animals that are already anesthetised with gas.	High cost. Anaesthetic and euthanasia properties of the gas used should be known. Isoflurane has a pungent odour. Methoxyflu-rane's action is slow and dog may become agitated.
Electrical	Electrocution	Cardiac fibrillation occurs before onset of unconscious-ness, causing severe pain if dog is conscious. Pain can also be caused by violent extension of the limbs, head and neck. Method may not be effective if insufficient current applied.	Only use on unconscious dog. ~~Dogs should be unconscious before being electrocuted~~. This can be accomplished by electrical stunning (current through the brain to produce an instantaneous stun) or anaesthesia. Electrodes should span the brain in order that the current passed through the brain in order to achieve an effective stun. Death would result from current passed through the heart of an unconscious animal. Proper equipment and trained operator is essential.	May be hazardous for operator, who should use protective equipment (boots and gloves).	Low cost.	Need to render animal unconscious. ~~Inhumane if performed on conscious dog.~~ May raise aesthetic objections.

KEY to abbreviations used in Table 1:
IV: intravenous
IP: intraperitoneal
IC: intracardiac

Annex XIII (contd)

Article 7.7.7.

Monitoring and evaluation of dog population control programmes

1. Monitoring and evaluation allows for comparison of important indicators against the baselines measured during initial assessment (see Article 7.7.5.). The three main reasons for carrying out monitoring and evaluation are:

   a. to help improve performance, by highlighting both problems and successful elements of interventions;

   b. for accountability, to demonstrate that the programme is achieving its aims;

   c. assuming methods are standardised, to compare the success of strategies used in different locations and situations.

2. Monitoring is a continuous process that aims to check the programme progress against targets and allows for regular adjustments. Evaluation is a periodic assessment, usually carried out at particular milestones to check the programme is having the desired and stated impact. These procedures involve the measurement of 'indicators' that are chosen because they reflect important components of the programme at different stages. Selection of suitable indicators requires clear planning of what the programme is aiming to achieve, the best selection of indicators will be one that reflects the interest of all relevant stakeholders. Standardised methodology will facilitate comparison of data from subsequent evaluations and performance between different projects. Indicators can be direct measurements of an area targeted to change (e.g. population of free roaming dogs on public property) or indirect measures that reflect change in a targeted area.

3. Elements that should generally be monitored and evaluated include:

   a. dog population size, separated into sub-populations according to ownership and restriction of movement (i.e. roaming unrestricted or restricted by an owner);

   b. dog welfare, in the target population (e.g. body condition score, skin conditions and injuries or lameness) and as a result of the programme (if interventions involve direct handling of dogs, the welfare of the dogs as result of this handling should be monitored);

   c. prevalence of zoonotic diseases, such as rabies, in both the animal and human population;

   d. responsible animal ownership, including measures of attitudes and understanding of responsible ownership and evidence that this is translating into responsible behaviour.

4. There are many sources of information for monitoring and evaluation purposes, including:

   a. feedback from the local community (e.g. through the use of structured questionnaires, focus groups or 'open format' consultation processes);

   b. records and opinions obtained from relevant professionals (e.g. *veterinarians*, medical doctors, law enforcement agencies, educators);

   c. animal based measurements (e.g. direct observation surveys of population size and welfare status).

5. The output of activities against budget should be carefully recorded in order to evaluate the effort (or cost) against the outcomes and impact (or benefit) that are reflected in the results of monitoring and evaluation.

Article 7.7.8.

An overview of appropriate methods for estimating the size of dog populations

Population estimates are necessary for making realistic plans for dog population management and zoonosis control, and for monitoring the success of such interventions. However, for designing effective management plans, data on population sizes alone are insufficient. Additional information is required, such as degrees of supervision of owned dogs, the origin of ownerless dogs, accessibility, etc.

The term 'owned' may be restricted to a dog that is registered with licensing authorities, or it may be expanded to unregistered *animals* that are somewhat supervised and receive shelter and some form of care in individual households. Owned dogs may be well supervised and restrained at all times, or they may be left without control for various time periods and activities. Dogs without owners that claim responsibility may still be accepted or tolerated in the neighbourhood, and individuals may provide food and protection. Such *animals* are sometimes called 'community owned dogs' or 'neighbourhood dogs'. For an observer it is frequently impossible to decide if a free roaming dog belongs to someone or not.

The choice of methods for assessing the size of a dog population depends on the ratio of owned versus ownerless dogs, which may not always easy to judge. For populations with a large proportion of owned dogs it may be sufficient to consult dog registration records or to conduct household surveys. These surveys should establish the number of owned dogs and the dog to human ratio in the area. In addition, questions on dog reproduction and demographics, care provided, zoonosis prevention, dog bite incidence, etc. may be asked. ~~Sample questionnaires can be found in the "Guidelines for Dog Population Management" (WHO/WSPA 1990).~~ Standard polling principles should be applied.

If the proportion of ownerless dogs is high or difficult to assess, then one should resort to more experimental approaches. Methods borrowed from wildlife biology can be applied. ~~These methods are described WHO/WSPA's "Guidelines for Dog Population Management" (1990), and in more detail in numerous professional publications and handbooks, such as Bookhout (1994) and Sutherland (2006).~~ Being generally diurnal and tolerant to human proximity, dogs lend themselves to direct observation and the application of mark-recapture techniques. Nevertheless, a number of caveats and limitations have to be taken into account. Firstly, the risk of zoonotic disease transmission is increased through close physical contact. Also, the methods are relatively labour intensive, they require some understanding of statistics and population biology, and most importantly, they are difficult to apply to very large areas. One should take into account that dog distribution is non-random, that their populations are not static, and that individual dogs are fairly mobile.

Counting of dogs visible in a defined area is the simplest approach to getting information on population size. One has to take into account that the visibility of dogs depends on the physical environment, but also on dog and human activity patterns. The visibility of *animals* changes with the time of the day and with seasons as a function of food availability, shelter (shade), disturbance, etc. Repeated standardized counting of dogs visible within defined geographical localities (e.g. wards) and specific times will provide indications of population trends. Direct counting is most reliable if it is applied to small and relatively confined dog populations, e.g. in villages, where it might be possible to recognize individual dogs based on their physical appearance.

Methods using mark-recapture procedures are often considered more reliable. However, they also produce trustworthy results only when a number of preconditions are met. Mortality, emigration and recruitment into the population should be minimal during the census period. One may be able to incorporate corrective factors into the calculations.

Annex XIII (contd)

It is therefore important that the recommended census procedures are applied at times of low dispersal and that one selects study plots of shape and size that minimize the effect of dog movements in and out of the observation area. Census surveys should be completed within a few days to a maximum of two weeks in order to reduce demographic changes. In addition, all individuals in the population should have an equal chance of being counted. This is a highly improbable condition for dogs, whose visibility depends on ownership status and degrees of supervision. It is therefore recommended that the investigator determines what fraction of the total population he/she might cover with an observational method and how much this part overlaps with the owned dog segment that he/she assesses with household surveys.

There are essentially two ways to obtain a population estimate if it is possible, in a defined area and within a few days, to tag a large number of dogs with a visible mark, e.g. a distinctive collar or a paint smudge. The first method requires that the capture (marking) effort remains reasonably constant for the whole length of the study. By plotting the daily number of dogs marked against the accumulated total of marked dogs for each day one can extrapolate the value representing the total number of dogs in the area. More commonly used in wildlife studies are mark recapture methods ~~(Peterson-Jackson, Lincoln indices)~~. Dogs are marked (tagged) and released back into the population. The population is subsequently sampled by direct observation. The number of marked and unmarked dogs is recorded. One multiplies the number of dogs that were initially marked and released by the number of subsequently observed dogs divided by the number of dogs seen as marked during the re-observation to obtain a total population estimate. ~~Examples for the two methods are given in WHO/WSPA's "Guidelines for Dog Population Management" (1990).~~

Since the dog populations of entire countries, states, provinces or even cities are much too large for complete assessment, it is necessary to apply the methods summarized above to sample areas. These should be selected (using common sense) so that results can be extrapolated to larger areas.

~~BOOKHOUT T.A. (ed), 1994: Research and Management Techniques for Wildlife and Habitats, 5th ed. The Wildlife Society, Bethesda, Maryland, 740p.~~

~~SUTHERLAND W.J. (ed), 2006: Ecological Census Techniques – A Handbook, 2nd ed. Cambridge University Press, Cambridge, 448 p.~~

~~WHO/WSPA, 1990: Guidelines for Dog Population Management. WHO/ZOON/90.165. WHO, Geneva, 116 p.~~

~~ text deleted

CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND EDUCATION

EU comments

The EU notes with satisfaction that its main concerns were taken into account during the adoption of this chapter at General Session in May 2010. The EU also supports the amendments proposed by the Code Commission in this latest version.

However, the EU would like to reiterate its previous comments concerning Articles 7.8.4 – 1. Project Proposal Reviews, 7.8.5 (2) – Veterinarians, 7.8.6 Provision of veterinary care and 7.8.7 - Source of animals.

Preamble: The purpose of this chapter is to provide advice and assistance for OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live *animals* in research and education[1]. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in this chapter in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of national, regional and institutional jurisdictions and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live *animals* in research and education. The OIE Guiding Principles for Animal Welfare state that such use makes a major contribution to the wellbeing of people and *animals* and emphasise the importance of the Three Rs (see Article 7.8.3.). Most scientists and members of the public agree that the *animals* should only be used when necessary; ethically justified (thereby avoiding unnecessary duplication of animal-based research); and when no other alternative methods, not using live *animals*, are available; that the minimum number of *animals* should be used to achieve the scientific or educational goals; and that such use of *animals* should cause as little pain and/or distress as possible. In addition, animal suffering is often recognised separately from pain and distress and should be considered alongside any lasting harm which is expected to be caused to *animals*.

The OIE emphasises the need for humane treatment of *animals* and that good quality science depends upon good *animal welfare*. It is the responsibility of all involved in the use of *animals* to ensure that they give due regard to these recommendations. In keeping with the overall approach to *animal welfare* detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the *animal*.

The OIE recognises the significant role of *veterinarians* in animal-based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of *animals* has an ethical responsibility for the *animals*' *welfare*. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum *welfare* for the *animals* used.

The OIE recommends that records on animal use should be maintained at an institutional level, as appropriate to the institution and project proposals and species used. Key events and interventions should be recorded to aid decision making and promote good science and *welfare*. A summary of these records may be gathered on a national basis and be published to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

Article 7.8.1.

Definitions

Biocontainment: means the system and procedures designed to prevent the accidental release of biological material including allergens.

Bioexclusion: means the prevention of the unintentional transfer of adventitious organisms with subsequent *infection* of *animals*, resulting in adverse effects on their health or suitability for research.

Biosecurity: means a continuous process of *risk assessment* and *risk management* designed to minimise or eliminate microbiological *infection* with adventitious organisms that can cause clinical *disease* in the infected *animals* or humans, or make *animals* unsuitable for biomedical research.

Annex XIII (contd)

Cloned animal: means a genetic copy of another living or dead *animal* produced by somatic cell nuclear transfer or other reproductive technology.

Distress: means the state of an *animal*, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Endangered species: means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Environmental enrichment: means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive *animal*'s environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as well as provide cognitive stimulation.

Ethical review: means consideration of the validity and justification for using *animals* including: an assessment and weighing of the potential harms for *animals* and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

~~**Euthanasia:** means the act of inducing *death* using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to the *animal*.~~

Harm-benefit analysis: means the process of weighing the likely adverse effects (harms) to the *animals* against the benefits likely to accrue as a result of the proposed project.

Humane endpoint: means the point in time at which an experimental *animal*'s pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the *animal* from the study, or humanely killing the *animal*.

Operant conditioning: means the association that an *animal* makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the *animal*can be modified (e.g. increased or decreased in frequency or intensity).

Pain: means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

Project proposal (sometimes called protocol): means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the *animals*, and includes ethical considerations.

Suffering: means an unpleasant, undesired state of being which is the outcome of the impact on an *animal*of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good *welfare*.

Article 7.8.2.

Scope

This chapter applies to *animals* as defined in the *Terrestrial Code* (excluding bees) bred, supplied and/or used in research (including testing) and higher education. *Animals* to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Members should consider both the species and the developmental stage of the *animal*n implementing these standards.

Article 7.8.3.

The Three Rs

The internationally accepted tenet, the 'Three Rs', comprises the following alternatives:

1. replacement refers to the use of methods utilizing cells, tissues or organs of *animals* (relative replacement), as well as those that do not require the use of *animals* to achieve the scientific aims (absolute replacement);
2. reduction refers to the use of methods that enable researchers to obtain comparable levels of information from fewer *animals* or to obtain more information from the same number of *animals*;
3. refinement refers to the use of methods that prevent, alleviate or minimise pain, suffering, distress or lasting harm and/or enhance *welfare* for the *animals* used. Refinement includes the appropriate selection of relevant species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity. Opportunities for refinement should be considered and implemented throughout the lifetime of the *animal* and include, for example, housing and transportation as well as procedures and euthanasia.

Article 7.8.4.

The oversight framework

The role of a *Competent Authority* is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of authorisation (such as licensing or registering of institutions, scientists, and/or projects) and compliance which may be assessed at the institutional, regional and/or national level.

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and *welfare*. This may be accomplished by a single body or distributed across different groups. Different systems of oversight may involve *animal welfare* officers, regional, national or local committees or bodies. An institution may utilise a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee, Animal Welfare Body or Animal Care Committee) to deliver some or all of this oversight framework. It is important that the local committee reports to senior management within the institution to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.

Ethical review of animal use may be undertaken by regional, national or local ethical review bodies or committees. Consideration should be given on how to ensure impartiality and independence from all those serving on the committees.

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

a) one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;

b) one *veterinarian*, with the necessary expertise to work with research *animals*, whose specific role is to provide advice on the care, use and *welfare* of such *animals*;

c) one public member to represent general community interests who is independent of the science and care of the *animals* and is not involved in the use of *animals* in research.

Additional expertise may be sought from the animal care staff, as these professional and technical staff are centrally involved in ensuring the *welfare* of *animals* used. Other participants, especially in relation to ethical review, may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted. It may be appropriate, in teaching institutions, to involve student representation.

Oversight responsibilities include three key elements:

1. Project proposal review

The purpose of the project proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

Project proposals, or significant amendments to these, should be reviewed and approved prior to commencement of the work. The proposal should identify the person with primarily responsibility for the project and should include a description of the following elements, where relevant:

a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health or *welfare*, the environment, or the advancement of biological knowledge;

b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the oversight body or committees who may be dealing with matters outside their specific field. Subject to safeguarding confidential information, such summaries may be made publicly available;

c) the experimental design, including justification for choice of species, source and number of *animals*, including any proposed reuse;

d) the experimental procedures;

~~EU Comment~~

~~Under section "1. Project proposal review" of Art 7.8.4, the EU would like to add a new point between points c) and d) as follows:~~

~~"x) statistical design and data analysis: study designs should be based on power calculations optimising data generation and data analysis to obtain the information sought with a minimum number of animals;~~ ***~~"~~***

~~Justification~~

~~Statistical design of a study presents ample opportunities to reduce animal numbers in line with the Reduction principle of the Three Rs. Therefore it is essential that the project review includes a critical assessment of the proposed statistical design of the study and its justifications.~~

e) methods of handling and restraint and consideration of refinements such as animal training and operant conditioning;

f) the methods to avoid or minimise pain, discomfort, distress, suffering or lasting impairment of physical or physiological function, including the use of anaesthesia and/or analgesia and other means to limit discomfort such as warmth, soft bedding and assisted feeding;

g) application of humane endpoints and the final disposition of *animals*, including methods of euthanasia;

h) consideration of the general health, husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;

i) ethical considerations such as the application of the Three Rs and a harm/benefit analysis; the benefits should be maximised and the harms, in terms of pain and distress, should be minimized;

j) an indication of any special health and safety risks; and

k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, staff trained and found competent to perform the procedures described in the proposed project).

The oversight body has a critical responsibility in determining the acceptability of project proposals, taking account of the animal welfare implications, the advancement of knowledge and scientific merit, as well as the societal benefits, in a risk-based assessment of each project using live animals.

Following approval of a project proposal, consideration should be given to implementing an independent (of those managing the projects) oversight method to ensure that animal activities conform with those described in the approved project proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry and experimental procedures; observations made by the veterinary staff during their rounds; or by inspections by the oversight body, which may be the local committee, animal welfare officer, compliance/quality assurance officer or government inspector.

EU Comment

In the above point 1) of Art 7.8.4, the EU would like to reiterate its previous comment by adding the following point l):

l) "the duration of approval of a project should normally be defined (e.g. up to five years) and progress achieved should be reviewed in considering renewal of a project approval."

Justification

To ensure high level of animal welfare and facilitate a proper oversight, it is important for the projects are reviewed after a period of to be limited in time. This will allow ensure the latest techniques on the Three Rs and the best practice to be are implemented in a timely fashion and without unnecessary delay.

2. Facility inspection

There should be regular inspections of the facilities, at least annually. These inspections should include the following elements:

a) the *animals* and their records, including cage labels and other methods of animal identification;

b) husbandry practices;

c) maintenance, cleanliness and security of the facility;

d) type and condition of caging and other equipment;

e) environmental conditions of the *animals* at the cage and room level;

f) procedure areas such as surgery; necropsy and animal research laboratories;

g) support areas such as washing equipment; animal feed, bedding and drug storage locations;

h) occupational health and safety concerns.

Principles of *risk management* should be followed when determining the frequency and nature of inspections.

3. Ethical evaluation

The ethical evaluation reflects the policies and practices of the institution in complying with regulations and relevant guidance. It should include consideration of the functioning of the local committee; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of *animals*; and occupational health and safety. The programme should be reviewed regularly. A requirement for the components of such a programme should be included in relevant regulations to empower the *Competent Authority* to take appropriate action to ensure compliance.

Article 7.8.5.

Assurance of training and competency

An essential component of the animal care and use programme is the assurance that the personnel working with the *animals* are appropriately trained and competent to work with the species used and the procedures to be performed, including ethical considerations. A system (institutional, regional or national) to assure competency should be in place, which includes supervision during the training period until competence has been demonstrated. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given their overarching responsibility for the animal care and use programme, should be knowledgeable about issues related to the competence of staff.

1. Scientific staff

   Researchers using *animals* have a direct ethical and legal responsibility for all matters relating to the *welfare* of the *animals* in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national and/or local regulatory framework and institutional policies. The laboratory *animalveterinarian* is often a resource for this and other training. Scientific staff should have demonstrated competency in procedures related to their research (e.g. surgery, anaesthesia, sampling and administration, etc.).

2. Veterinarians

   It is important that *veterinarians* working in an animal research environment have veterinary medical knowledge and experience in the species used, including the normal behaviour of the species, and they should understand research methodology. Relevant approvals issued by the *veterinary statutory body* and appropriate national or regional schemes (where these exist) should be adopted as the reference for veterinary training.

EU comment

In the above point 2) of Art 7.8.5, the EU would like to reiterate its previous comment for future consideration as follows:

"Veterinarians.

It is important that veterinarians working in an animal research environment have veterinary medical knowledge and experience in the species used~~, including normal behaviour, and they should understand research methodology~~. Furthermore, they should be educated and experienced in the normal behaviour, behavioural needs, stress responses and adaptability of the species, as well as research methodologies."

Justification

It is important that the veterinarians have also acquired the necessary experience to allow competent analysis and detection of changes in normal behaviour and recognition of early signs of stress.

3. Animal care staff

   Animal care staff should receive training that is consistent with the scope of their work responsibilities and have demonstrated competency in the performance of these tasks.

4. Students

   Students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc.) when such methods can effectively reduce or replace the use of live *animals* and still meet learning objectives. Wherever it is necessary for students to participate in classroom or research activities involving live *animals*, they should receive appropriate supervision in the use of *animals* until such time that they have demonstrated competency in the related procedure(s).

5. Members of the local oversight committee or others involved with oversight

   Continuing education about the use of *animals* in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

Occupational health and safety training for research animal related risks should be provided as part of the assurance of training and competency for personnel. This might include consideration of human infectious *diseases* which may infect research *animals* and thus compromise research results, as well as possible *zoonoses*. Personnel should understand that there are two categories of hazards, those that are intrinsic to working in an animal facility and those associated with the research. Specific training may be required for particular species, for specific procedures, and for the use of appropriate protective measures for personnel who may be exposed to animal allergens. Research materials, such as chemicals of unknown toxicity, biological agents and radiation sources, may present special hazards.

Article 7.8.6.

Provision of veterinary care

Adequate veterinary care includes responsibility for promoting an *animal*'s health and *welfare* before, during and after research procedures and providing advice and guidance based on best practice. Veterinary care includes attention to the physical and behavioural status of the *animal*. The *veterinarian* should have authority and responsibility for making judgements concerning *animal welfare*. Veterinary advice and care should be available at all times.

EU comment

At the end of the above paragraph of Article 7.8.6, the EU would like to reiterate its previous comment as follows:

"Veterinary advice ~~and care~~ should be available at all times. In exceptional circumstances, where species unfamiliar to the veterinarian are involved, it may be acceptable for a suitably qualified non-veterinary expert to provide advice in place of the veterinarian."

Justification

A veterinarian may not always be the most appropriate or best qualified person in cases of unusual species such as reptiles. However veterinary advice should be the norm and non-veterinary advice sought only in exceptional circumstances and from recognised experts.

1. Clinical responsibilities

   Preventive medicine programmes that include vaccinations, ectoparasite and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular animal species and source. Disease surveillance is a major responsibility of the *veterinarian* and should include routine monitoring of colony *animals* for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical *diseases*. The *veterinarian* should have the authority to use appropriate treatment or control measures, including euthanasia if indicated, and access to appropriate resources, following diagnosis of an animal *disease* or injury. Where possible, the *veterinarian* should discuss the situation with the scientist to determine a course of action consistent with experimental goals. Controlled drugs prescribed by the veterinary staff should be managed in accordance with applicable regulations.

2. Post-mortem examinations

   In the case of unexpected *diseases* or *deaths*, the *veterinarian* should provide advice based on post-mortem examination results. As part of health monitoring, a planned programme of post-mortem examinations may be considered.

3. Veterinary medical records

   Veterinary medical records, including post-mortem records, are considered to be a key element of a programme of adequate veterinary care for *animals* used in research and education. Application of performance standards within the veterinary medical record programme allows the *veterinarian* to effectively employ professional judgment, ensuring that the *animal*receives the highest level of care available.

4. Advice on zoonotic risks and notifiable diseases

The use of some species of *animals* poses a significant risk of the transmission of zoonotic *disease* (e.g. some nonhuman primates). The *veterinarian* should be consulted to identify sources of *animals* that minimise these risks and to advice on measures that may be taken in the animal facility to minimize the risk of transmission (e.g. personal protective equipment, appropriate *désinfection* procedures, air pressure differentials in animal holding rooms, etc.). *Animals* brought into the institution may carry *diseases* that require notification to government officials. It is important that the *veterinarian* be aware of, and comply with, these requirements.

5. Advice on surgery and postoperative care

A programme of adequate veterinary care includes input into the review and approval process of preoperative, surgical and postoperative procedures by an appropriately qualified *veterinarian*. A *veterinarian*'s inherent responsibility includes providing advice concerning preoperative procedures, aseptic surgical techniques, the competence of staff to perform surgery and the provision of postoperative care. Veterinary oversight should include the detection and resolution of emerging patterns of surgical and post procedural complications.

6. Advice on analgesia, anaesthesia and euthanasia

Adequate veterinary care includes providing advice on the proper use of anaesthetics, analgesics, and methods of euthanasia.

7. Advice on humane endpoints

Humane endpoints should be established prior to commencement of a study in consultation with the *veterinarian* who also plays an important role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the *veterinarian* has the authority to ensure euthanasia or other measures are carried out as required to relieve pain and distress unless the project proposal approval specifically does not permit such intervention on the basis of the scientific purpose and the ethical evaluation.

Ideal humane endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardising the study's objectives. In consultation with the *veterinarian*, humane endpoints should be described in the project proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, *death* (other than euthanasia) as a planned endpoint is considered ethically unacceptable.

Article 7.8.7.

Source of animals

Animals to be used for research should be of high quality to ensure the validity of the data.

1. Animal procurement

Animals should be acquired legally. It is preferable that *animals* are purchased from recognised sources producing or securing high quality *animals*.

Purpose bred *animals* should be used whenever these are available and *animals* that are not bred for the intended use should be avoided unless there is compelling scientific justification or are the only available and suitable source. In the case of farm *animals*, non traditional breeds and species, and *animals* captured in the wild, non purpose bred *animals* are often used to achieve specific study goals. The use of wild caught nonhuman primates is generally discouraged.

EU comment

In the last sentence of the above paragraph of Art 7.8.7, the EU would like to reiterate its earlier comment as follows:

"The use of wild caught nonhuman primates is generally discouraged. Only purpose-bred animals should be used in line with the ultimate goal of shifting towards the use of second or higher generation purpose bred (F2+) animals."

Justification

For scientific, animal welfare and biodiversity reasons, the non-human primates used in experiments should be of second or higher generation, well characterised, purpose bred animals. Attempts should be made to move towards this goal and breeding strategies should be put in place to further this aim.

2. Documentation

Relevant documentation related to the source of the *animals*, such as health and other veterinary certification, breeding records, genetic status and animal identification, should accompany the *animals*.

3. Animal health status

The health status of *animals* can have a significant impact on scientific outcomes. There also may be occupational health and safety concerns related to animal health status. *Animals* should have appropriate health profiles for their intended use. The health status of *animals* should be known before initiating research.

4. Genetically defined animals

A known genetic profile of the *animals* used in a study can reduce variability in the experimental data resulting from genetic drift and increase the reproducibility of the results. Genetically defined *animals* are used to answer specific research questions and are the product of sophisticated and controlled breeding schemes which should be validated by periodic genetic monitoring. Detailed and accurate documentation of the colony breeding records should be maintained.

5. Genetically altered (also genetically modified or genetically engineered) or cloned animals ~~(also genetically modified animal and genetically engineered animal)~~.

A genetically altered ~~or cloned~~ *animals~~*~~ is one ~~an *animal*~~ that has had undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an *animal*(s), where they have inherited the modification. If genetically altered or cloned *animals* are used, such use should be conducted in accordance with relevant regulatory guidance. With such *animals*, as well as harmful mutant lines arising from spontaneous mutations and induced mutagenesis, consideration should be given to addressing and monitoring special husbandry and *welfare* needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic and phenotypic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised *animals*.

6. Animals captured in the wild

If wild *animals* are to be used, the capture technique should be humane and give due regard to human and animal health, *welfare* and safety. Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the project proposal.

7. Endangered species

Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.

8. Transport, importation and exportation

Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen status, with care to ensure appropriate physical containment of the *animals* as well as

exclusion of contaminants. The amount of time *animals* spend on a journey should be kept to a minimum. It is important to ensure that there is a well constructed journey plan, with key staff identified who have responsibility for the *animals* and that relevant documentation accompanies *animals* during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.

9. Risks to biosecurity

In order to minimise the risk of contamination of *animals* with unwanted infectious microorganisms or parasites that may compromise the health of *animals* or make them unsuitable for use in research, the microbiological status of the *animals* should be determined and regularly assessed. Appropriate biocontainment and bioexclusion measures should be practised to maintain their health status and, if appropriate, measures taken to prevent their exposure to certain human or environmental commensals.

Article 7.8.8.

Physical facility and environmental conditions

A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the *animals* to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. *Animals* should normally be housed in facilities designed for that purpose. Security measures (e.g. locks, fences, cameras, etc.) should be in place to protect the *animals* and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of *welfare* concern.

Important environmental parameters to consider include ventilation, temperature and humidity, lighting and noise:

1. Ventilation

The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an *animal*'s primary enclosure and are thus important determinants of its microenvironment. Factors to consider when determining the air exchange rate include range of possible heat loads; the species, size, and number of *animals* involved; the type of bedding or frequency of cage changing; the room dimensions; and the efficiency of air distribution from the secondary to the primary enclosure. Control of air pressure differentials is an important tool for biocontainment and bioexclusion.

2. Temperature and humidity

Environmental temperature is a physical factor which has a profound effect on the *welfare* of *animals*. Typically, animal room temperature should be monitored and controlled. The range of daily fluctuations should be appropriately limited to avoid repeated demands on the *animals*' metabolic and behavioural processes to compensate for large changes in the thermal environment as well as to promote reproducible and valid scientific data. Relative humidity may also be controlled where appropriate for the species.

3. Lighting

Light can affect the physiology, morphology and behaviour of various *animals*. In general, lighting should be diffused throughout an animal holding area and provide appropriate illumination for the *welfare* of the *animals* while facilitating good husbandry practices, adequate inspection of *animals* and safe working conditions for personnel. It may also be necessary to control the light/dark cycle.

4. Noise

Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy *animals*, such as dogs, pigs, goats and nonhuman primates, should be housed in a manner which ensures they do not adversely affect the *welfare* of quieter *animals*, such as rodents, rabbits and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources.

Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.

EU comment

After the first sentence of paragraph "4. Noise" of Art 7.8.8 above, the EU would like to add a sentence as follows:

"Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noise levels including ultrasound, should not adversely affect animal welfare. Noisy animals, such as dogs, pigs, goats and nonhuman primates, should be housed in a manner which ensures they do not adversely affect the welfare of quieter animals, such as rodents, rabbits and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered."

Justification

The current text concerns mainly noise originating from either humans or other animals. A performance based general principle should be added in the beginning of the text covering noise before going into more details. The general principle will cater for any source of noise including for example from technical equipment such as biosafety working benches.

Article 7.8.9.

Husbandry

Good husbandry practices enhance the health and *welfare* of the *animals* used and contributes to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the *animal*, and should minimise stress to the *animal*. During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the *animals*' *welfare*.

1. Transportation

   Transportation is a typically stressful experience. Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Social *animals* should be transported in established pairs or groups and maintained in these on arrival.

2. Acclimatisation

   Newly received *animals* should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the *animals*. Facilities should be available to isolate *animals* showing signs of ill health.

3. Cages and pens

Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the *animals* are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese *animals*, and group or individual housing). Both the quantity and quality of space provided is important. Whenever it is appropriate, social *animals* should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the *animals*.

4. Enrichment

Animals should be housed with a goal of maximising species appropriate behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the *animals* and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the *animals* or people, nor interfere with the scientific goals.

5. Feeding

Provision should be made for each *animal* to have access to feed to satisfy its physiological needs. Precautions should be taken in packing, transporting, storing and preparing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.

6. Water

Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.

7. Bedding

Animals should have appropriate bedding provided, with additional nesting material if appropriate to the species. Animal bedding is a controllable environmental factor that can influence experimental data and animal welfare. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the animals clean and dry.

8. Hygiene

The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading infection between animals through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.

9. Identification

Animal identification is an important component of record keeping. Animals may be identified individually or by group. Where it is desirable to individually identify animals, this should be done by a reliable and the least painful method.

10. Handling

Staff dealing with *animals* should have a caring and respectful attitude towards the *animals* and be competent in handling and restraint. Familiarising *animals* to handling during routine husbandry and procedures reduces stress both to *animals* and personnel. For some species, for example dogs and non-human primates, a training programme to encourage cooperation during procedures can be beneficial to the *animals*, the animal care staff and the scientific programme. For certain species, social contact with humans should be a priority. However, in some cases handling should be avoided. This may be particularly the case with wild *animals*. Consideration should be given to setting up habituation and training programmes suitable for the *animals*, the procedures and length of projects.

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1. Wherever the term "research" is used, it includes basic and applied research, testing and the production of biological materials; "education" includes teaching and training.

Annex XIV

CHAPTER 8.1

ANTHRAX

EU comment

The EU can support the proposed changes.

However, the EU still question the structure of this chapter: the first paragraph and the articles 14 and 15, and to a lesser extent 12 and 13 seem to indicate that it should be in Volume 1, while articles 2 to eleven are relevant in the Volume 2. This should be better addressed by the TAHSC.

Article 8.1.1.

General provisions

This chapter is intended to manage the human and animal health risks associated with the presence of *Bacillus anthracis* in *commodities* and the environment.

There is no evidence that anthrax is transmitted by *animals* before the onset of clinical and pathological signs. Early detection of *outbreaks*, quarantine of affected premises, destruction of diseased *animals* and fomites, and implementation of appropriate sanitary procedures at *abattoirs* and dairy factories will ensure the safety of products of animal origin intended for human consumption.

For the purposes of the *Terrestrial Code*, the *incubation period* for anthrax shall be 20 days.

Anthrax should be notifiable in the whole country.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual.*

When authorising import or transit of *commodities* covered in the chapter, with the exception of those listed in Article 8.1.2.,*Veterinary Authorities* should require the conditions prescribed in this chapter.

Article 8.1.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any anthrax related conditions: semen and *in vivo* derived cattle embryos collected and handled in accordance with Chapters 4.5., 4.6. and 4.7., as relevant.

Article 8.1.3.

Recommendations for the importation of ruminants, equines and pigs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of anthrax on the day of shipment;

AND

2. were kept for the 20 days prior to shipment in an *establishment* where no *case* of anthrax was officially declared during that period; or

3. were vaccinated, not less than 20 days and not more than 6 months prior to shipment in accordance with the *Terrestrial Manual*.

Article 8.1.4.

Recommendations for the importation of fresh meat and meat products destined for human consumption

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products originate from *animals* which:

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and

2. were not vaccinated against anthrax using live vaccine during the 21 days prior to *slaughter* or a longer period depending on the manufacturer's recommendations; and

3. come from *establishments* which are not placed under movement restriction on account of anthrax and in which there has been no *case* of anthrax during the 20 days prior to *slaughter*.

Article 8.1.5.

Recommendations for the importation of hides, skins and hair (from ruminants, equines and pigs)

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products ~~originate from *animals* which~~:

1. originate from *animals* which :

   a. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and

   ~~2~~b. come from *establishments* which are not placed under movement restriction on account of anthrax;

OR

2. for hair, have been treated in accordance with the recommendations in Article 8.1.11.

Article 8.1.6.

Recommendations for the importation of wool

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the product~~s~~:

1. originate~~s~~ from live animal; and

2. originates from ~~*establishments* where no *case* of anthrax has been reported since the previous shearing of all~~ *animals* which, at the time of shearing, were part of a *flock* that was not subject to restrictions imposed for the control of anthrax;

OR

~~2~~3. have been treated in accordance with the recommendations in Article 8.1.11.

Article 8.1.7.

Recommendations for the importation of milk and milk products intended for human consumption

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the *milk* originates from *animals* showing no clinical signs of anthrax at the time of milking;

2. if the *milk* originates from *herds* or *flocks* that have had a *case* of anthrax within the previous 20 days, it has been chilled promptly and processed using a heat treatment at least equivalent to pasteurisation.

Article 8.1.8.

Recommendations for the importation of bristles (from pigs)

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products originate from *animals* which:

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and

2. come from establishments which are not placed under movement restriction on account of anthrax control;

OR

3. have been processed to ensure the destruction of *B. anthracis* by:

   a) boiling for 60 minutes; and

   b) drying in hot air.

Article 8.1.9.

Procedures for the inactivation of *B. anthracis* spores in skins and trophies from wild animals

In situations in which skins and trophies from wild *animals* may be contaminated with *B. anthracis* spores, the following *disinfection* procedure is recommended:

1. fumigation with ethylene oxide 500 mg/L, at relative humidity 20 – 40%, at 55°C for 30 minutes; or

2. fumigation with formaldehyde 400 mg/m³ at relative humidity 30%, at >15°C for 4 hours; or

3. gamma irradiation with a dose of 40 kGy.

Article 8.1.10.

Procedures for the inactivation of *B. anthracis* spores in bone-meal and meat-and-bone meal

In situations where raw materials used to produce bone meal or *meat-and-bone meal* may be contaminated with *B. anthracis* spores, ~~T~~the following inactivation procedure should be used ~~to inactivate any *B. anthracis* spores which may be present during the production of bone-meal or meat-and-bone meal from ruminants, equines and pigs~~:

1. the raw material should be reduced to a maximum particle size of 50 mm before heating; and

2. the raw material should be ~~heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar. Other industrial process demonstrating equivalent efficacy is also acceptable.~~ subjected to moist heat at one of the following temperature and time regimes:

   a) 105 ºC for at least 8 minutes ; or

   b) 100ºC for at least 10 minutes ; or

   c) 95 ºC for at least 25 minutes or;

d) 90ºC for at least 45 minutes or;

e) an industrial process demonstrated to be of equivalent efficacy.

Article 8.1.11.

Procedures for the inactivation of *B. anthracis* spores in wool and hair

In situations in which wool or hair may be contaminated with *B. anthracis* spores, the following ~~five step *disinfection*~~ procedures ~~is~~ are recommended:

1. gamma irradiation with a dose of 50 kGy; or

2. a five step washing procedure:

a) immersion in 0.25 – 0.3% soda liquor for 10 minutes at 40.5°C;

~~2~~b) immersion in soap liquor for 10 minutes at 40.5°C;

~~3~~c) immersion in 2% formaldehyde solution for 10 minutes at 40.5°C;

~~4~~d) a second immersion in 2% formaldehyde solution for 10 minutes at 40.5°C;

~~5~~e) rinsing on cold water followed by drying in hot air.

Article 8.1.12.

Procedures for the inactivation of *B. anthracis* spores in manure, dung and bedding

In situations in which manure, dung or bedding may be contaminated with *B. anthracis* spores, the following are recommended:

1. small volumes by incineration; or

2. chemothermal treatment by composting as follows:

a) mix with one of the following at a rate of 1 – 1.5L/m³;

i) 10% formaldehyde (approximately 30% formalin), or

ii) 4% gluteraldehyde (pH 8.0 – 8.5);

b) turn the material after 5 weeks;

c) leave for a further 5 weeks.

[Note: spontaneous combustion of the composting pile is possible.]

Article 8.1.13.

Procedures for the inactivation of *B. anthracis* spores in liquid manure (slurry)

In situations in which liquid manure (slurry) may be contaminated with *B. anthracis* spores, *disinfection* with formalin (35% aqueous solution of formaldehyde) with stirring for one hour daily is recommended:

1. for slurry up to 5% dry matter, 50 kg formalin per m³ for 4 days;

2. for slurry >5% and <10% dry matter, 100 kg formalin per m³ for 4 days.

Article 8.1.14.

Procedures for the disinfection of surfaces in animal houses, buildings contaminated with *B. anthracis*

In situations in which surfaces in animal houses, stables, *vehicles*, etc. may be contaminated with *B. anthracis* spores, the following three-step approach is recommended:

1. a preliminary *disinfection* should be carried out using one of the following disinfectants at a rate of 1 – 1.5 L/m³ for 2 hours;

    a) 10% formaldehyde (approximately 30% formalin); or

    b) 4% glutaraldehyde (pH 8.0 – 8.5);

2. all surfaces should be washed and scrubbed using ample hot water and, when cleaned and waste water is free from dirt particles, dried;

3. a final *disinfection* step should be carried out using one of the following disinfectants applied at a rate of 0.4 L/m³ for 2 hours;

    a) 10% formaldehyde (approximately 30% formalin), repeated after one hour; or

    b) 4% glutaraldehyde (pH 8.0 – 8.5), repeated after one hour; or

    c) 3% hydrogen peroxide; or

    d) 1% peracetic acid, repeated after one hour.

[Note: Formaldehyde and glutaraldehyde should not be used at temperatures below 10°C. Hydrogen peroxide and peracetic acid are not suitable in the presence of blood.]

Article 8.1.15.

Procedures for the fumigation of rooms contaminated with *B. anthracis*

Contaminated rooms which cannot be cleared before cleaning and *disinfection* can be fumigated to eliminate *B. anthracis* spores. The following procedure is recommended:

1. all windows, doors and vents to the outside should be sealed with heavy adhesive tape; and

Annex XIV (contd)

2. for rooms up to 30 m³, 4 L of water containing 400 ml of concentrated formalin (37% w/v formaldehyde) in an electric kettle (with a timing switch to turn it off) should be boiled away and the room left overnight. Room temperature should be >15°C.

[Note: Formaldehyde fumigation is hazardous and proper respirators should be on hand for operator safety. The effectiveness of the fumigation process should be verified by exposing dried discs of filter paper which have been dipped in a suspension of spores of B. subtilis var globigii or B. cereus or Sterne vaccine strain of B. anthracis and placed in the room before fumigation is started. At the end of fumigation, the discs should be placed on nutrient agar plates containing 0.1% histidine and incubated overnight at 37°C. If fumigation has been effective, there will be no bacterial growth.]

– text deleted

Annex XV

CHAPTER 8.2.

AUJESZKY'S DISEASE

EU comment

The EU thanks the OIE TAHSC and supports the proposed changes.

However, the chapter deserves more changes:

- There is no clear definition of AD and AD case, especially in relation to the susceptible or targeted species, and the role of wildlife.

- The Article 8.2.1 should therefore be updated taking into account the recent updates of similar articles. A proposal of modification is inserted in the article below.

Article 8.2.1.

General provisions

The Aujeszky's disease (AD) free or provisionally free status of a country or *zone* can only be determined if the following conditions are fulfilled:

1. a *risk assessment* has been conducted identifying all potential factors for AD occurrence and their historic perspective;

2. AD is notifiable in the whole country, and all clinical cases suggestive of AD are subjected to field and laboratory investigations;

3. an on-going awareness programme is in place to encourage reporting of all cases suggestive of AD in susceptible species;

4. the *Veterinary Authority* has current knowledge of, and authority over, all *establishments* containing pigs in the whole country;

5. domestic pigs are properly identified when leaving their *establishment* of origin with an indelible mark giving the identification number of their *herd* of origin; a reliable tracing back procedure is in place for all pigs leaving their *establishment* of origin.

An AD infected *establishment* means an *establishment* in which the virus has been isolated or identified, or a positive serological result (total or gE antibodies) has been confirmed in a *laboratory*.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the AD status of the *exporting country* or *zone*.

EU Comment

The EU proposes to restructure the article 8.2.1 as follows:

Article 8.2.1.

General provisions

Pigs are the natural host for Aujeszky's disease (AD) virus, although it can infect cattle, sheep, cats, dogs and rats causing fatal disease. The definition of pig includes all varieties of Sus scrofa, both domestic and wild.

For the purposes of the Terrestrial Code, Aujeszky's disease (AD) is defined as an infection of domestic pigs and captive wild pigs.

For the purposes of this chapter, a distinction is made between domestic pig and captive wild pig populations on the one hand and wild pig and feral pig populations on the other hand.

Domestic pig is defined as all domesticated pigs, permanently captive or farmed free range, used for the production of meat for consumption, for the production of other commercial products or for breeding these categories of pigs.

~~**An AD infected establishment means an establishment in which the virus has been isolated or identified, or a positive serological result (total or gE antibodies) has been confirmed in a laboratory.**~~

Standards for diagnostic tests and vaccines are described in the Terrestrial Manual.

A Member should not impose trade bans in response to a notification of infection with Aujeszky's disease virus in wild pigs according the Article 1.2.3. of the Terrestrial Code.

When authorising import or transit of the commodities covered in the chapter, with the exception of those listed in Article 8.2.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the AD status of the exporting country or zone.

Article 8.2.1.bis

Determination of the AD status of a country, zone or compartment

The Aujeszky's disease (AD) free or provisionally free status of a country or zone can only be determined ~~if~~ after considering the following ~~conditions are fulfilled~~ criteria in domestic and wild pigs, as applicable:

~~**1. a risk assessment has been conducted identifying all potential factors for AD occurrence and their historic perspective;**~~

~~2.~~1. AD is notifiable in the whole country, and all clinical ~~cases~~ signs suggestive of AD ~~are~~ should be subjected to appropriate field and /or laboratory investigations;

~~3.~~2. an on-going awareness programme ~~is~~ should be in place to encourage reporting of all cases suggestive of AD ~~in susceptible species~~;

~~4.~~3. the Veterinary Authority ~~has~~ should have current knowledge of, and authority over, all ~~establishments containing~~ domestic pigs in the ~~whole~~ country or zone;

4. the Veterinary Authority should have current knowledge about the population and habitat of wild pigs in the country or zone.

5. appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Chapter 1.4;

~~**domestic pigs are properly identified when leaving their establishment of origin with an indelible mark giving the identification number of their herd of origin; a reliable tracing back procedure is in place for all pigs leaving their establishment of origin.**~~

Article 8.2.2.

Safe commodities

When authorising import or transit of the following *commodities* and any products made from these, *Veterinary Authorities* should not require any AD related conditions, regardless of the AD status of the the *exporting country* or *zone*:

1. *fresh meat* of domestic and wild pigs not containing offal (head, and thoracic and abdominal viscera);

2. *meat products* of domestic and wild pigs not containing offal (head, and thoracic and abdominal viscera);

3. products of animal origin not containing offal (head, and thoracic and abdominal viscera).

Article 8.2.3.

AD free country or zone

1. Qualification

a) A country or *zone* may be considered free from the *disease* without formally applying a specific *surveillance* programme (historical freedom) if the *disease* has not been reported for at least 25 years, and if for at least the past 10 years:

~~a~~i) it has been a *notifiable disease*;

~~b~~ii) an early detection system has been in place;

~~c~~iii) measures to prevent the introduction of the AD virus into the country or *zone* have been in place;

~~d~~iv) no vaccination against the *disease* has been carried out;

~~e~~v) *infection* is not known to be established in wild swine, or measures have been implemented to prevent any transmission of the AD virus from wild swine to domestic pigs.

b) A country or *zone* which does not meet the conditions of the above paragraph may be considered free from AD when:

~~f~~i) animal health regulations to control the movement of *commodities* with the exception of those listed in Article 8.2.2. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least 2 years;

~~g~~ii) vaccination against AD has been banned for all domestic pigs in the country or *zone* for at least 2 years;

~~h~~iii) if AD has never been reported in the country or *zone*, serological surveys, with negative results, have been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter ~~X.X.~~ 1.4. ~~(under study)~~ no more than 3 years prior to qualification; the serological surveys should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or

~~i~~iv) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect every infected *establishment* and eradicate AD from it; the *surveillance* programme should be carried out in conformity with the recommendations in Chapter ~~X.X.~~ 1.4. ~~(under study)~~ and demonstrate that no *establishments* within the country or *zone* have had any clinical, virological or serological evidence of AD for at least 2 years.

~~In order for a country to reach free status, all of its *zones* should have reached AD free status.~~

v) In countries or *zones* with wild swine, measures should be implemented to prevent any transmission of the AD virus from wild swine to domestic pigs.

2. Maintenance of free status

In order to maintain its free status, a country or *zone* should comply with the following requirements:

~~F~~a) periodic serological surveys directed at the detection of antibodies to the whole AD virus should be carried out on a statistically significant number of breeding pigs, in conformity with the recommendations in Chapter ~~X.X.~~ 1.4. ~~(under study)~~;

~~G~~b) the importation of the *commodities* with the exception of those listed in Article 8.2.2. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant Articles of the present chapter;

~~H~~c) the ban on AD vaccination remains in force;

~~I~~d) measures aimed at preventing the transmission of the AD virus from wild swine to domestic pigs remain in force.

3. Recovery of free status

Should an AD *outbreak* occur in an *establishment* of a free country or *zone*, the status of the country or *zone* may be restored if either:

a) all the pigs in the *outbreak* have been slaughtered; and, during and after the application of this measure, an epidemiological investigation including clinical examination, and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a ~~5 kilometre~~ prescribed radius ~~of~~ from the *outbreak*, demonstrating that these *establishments* are not infected; or

b) vaccination with gE- deleted vaccines has been applied and:

i) a serological testing procedure (differential ELISA) has been implemented in the *establishments* where vaccination has been applied to demonstrate the absence of *infection*;

ii) the movement of pigs from these *establishments* has been banned, except for immediate *slaughter*, until the above procedure has demonstrated the absence of *infection*;

iii) all vaccinated *animals* have been slaughtered;

EU comment

The point iii) should be deleted. Indeed, the objective of marker/deleted vaccines is to allow the distinction between vaccinated and infected animals. Non infected animals should not have to be slaughtered. This point iii) is inconsistent with the recent modifications of other chapters, such as that on Classical Swine Fever.

iv) during and after the application of the measures described in points i) to iii) above, a thorough epidemiological investigation including clinical examination and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a ~~5 kilometre~~ prescribed radius ~~of~~ from the *outbreak*, demonstrating that these *establishments* are not infected.

Article 8.2.4.

AD provisionally free country or zone

1. Qualification

A country or *zone* may be considered as provisionally free from AD if the following conditions are complied with:

Annex XV (contd)

a) animal health regulations to control the movement of *commodities* with the exception of those listed in Article 8.2.2. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least 2 years;

b) if AD has never been reported in the country or *zone*, a serological survey, with negative results, has been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter ~~X.X.~~ 1.4. ~~(under study)~~ (at a level of confidence not sufficient to meet requirements for freedom); the serological survey should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or

c) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect infected *establishments* and eradicate AD from these *establishments*, the *herd* prevalence rate in the country or *zone* has not exceeded 1% for at least 3 years (the sampling procedure described in point 1e) of the definition of 'AD free establishment' should be applied within the *establishments* of the country or *zone*), and at least 90% of the *establishments* in the country or *zone* are qualified free;

d) in countries or *zones* with wild swine, measures should be taken to prevent any transmission of the AD virus between wild swine and domestic pigs.

2. Maintenance of provisionally free status

In order to maintain its provisionally free status, a country or *zone* should comply with the following requirements:

a) the measures described in points 1b) and 1d) above should be continued;

b) the percentage of infected *establishments* remains <1%;

c) the importation of the *commodities* with the exception of those listed in Article 8.2.2. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant Articles of the present chapter.

3. Recovery of provisionally free status

Should the percentage of infected *establishments* exceed 1% in a provisionally free country or *zone*, the status of the country or *zone* is cancelled and may be restored only once the percentage of infected *establishments* has remained <1% for at least 6 months, and this result is confirmed by a serological survey conducted in conformity with point 1c) above.

Article 8.2.5.

AD infected country or zone

For the purpose of this chapter, countries and *zones* which do not fulfil the conditions to be considered free or provisionally free of AD should be considered as infected.

Article 8.2.6.

AD free establishment

1. Qualification

To qualify as free from AD, an *establishment* should satisfy the following conditions:

a) it is under the control of the *Veterinary Authority*;

b) no clinical, virological or serological evidence of AD has been found for at least one year;

c) the introduction of pigs, semen and embryos/ova into the *establishment* is carried out in conformity with the import conditions for these *commodities* contained in the relevant articles of the present chapter;

d) vaccination against AD has not been carried out in the *establishment* for at least 12 months, and any previously vaccinated pigs are free from gE antibodies;

e) a number of breeding pigs from the *establishment* has been subjected, with negative results, to serological tests to the whole AD virus, applying a sampling procedure set out in conformity with the recommendations in Chapter ~~X.X.~~ 1.4. ~~(under study)~~; these tests should have been carried out on two occasions, at an interval of 2 months; for *establishments* that contain no breeding pigs, the tests should be carried out only once on a comparable number of fattening or weaning pigs;

f) a *surveillance* and control programme has been in place to detect infected *establishments* located within a ~~5 kilometre~~ prescribed radius ~~of~~ from the *establishment* and no *establishment* is known to be infected within this *zone*.

2. Maintenance of free status

For *establishments* located in an infected country or *infected zone*, the testing procedure described in point 1e) above should be carried out every 4 months.

For *establishments* located in a provisionally free country or *zone*, the testing procedure described in point 1e) above should be carried out every year.

3. Recovery of free status

Should a free *establishment* become infected, or should an *outbreak* occur within a ~~5 kilometre~~ prescribed radius ~~of~~ from a free *establishment*, the free status of the *establishment* should be suspended until the following conditions are met:

a) in the infected *establishment*:

i) all the pigs in the *establishment* have been slaughtered, or

ii) at least 30 days after removal of all infected *animals*, all breeding *animals* have been subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of 2 months;

b) in other *establishments* located within the ~~5 kilometre~~ prescribed radius *zone*: a number of breeding pigs from each *establishment* has been subjected, with negative results, to serological tests to the whole AD virus (non vaccinated *establishments*) or to gE antibodies (vaccinated *establishments*), applying the sampling procedure described in point 1e above.

Article 8.2.7.

Recommendations for importation from AD free countries or zones

for domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

Annex XV (contd)

1. showed no clinical sign of AD on the day of shipment;
2. come from an *establishment* located in an AD free country or *zone*;
3. have not been vaccinated against AD.

Article 8.2.8.

Recommendations for importation from AD provisionally free countries or zones

for domestic pigs for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of AD on the day of shipment;
2. have been kept exclusively in AD free *establishments* since birth;
3. have not been vaccinated against AD;
4. were subjected to a serological test to the whole AD virus, with negative results, within 15 days prior to shipment.

Article 8.2.9.

Recommendations for importation from AD infected countries or zones

for domestic pigs for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of AD on the day of shipment;
2. were kept exclusively in AD free *establishments* since birth;
3. have not been vaccinated against AD;
4. were isolated in the *establishment* of origin or a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.10.

Recommendations for importation from AD provisionally free countries or zones or AD infected countries or zones

for domestic pigs for slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. a *surveillance* and control programme is in place in the country or *zone* to detect infected *establishments* and eradicate AD;
2. the *animals*:
    a) are not being eliminated as part of an eradication programme;

b) showed no clinical sign of AD on the day of shipment;

c) have been kept exclusively in AD free *establishments* since birth; or

d) have been vaccinated against AD at least 15 days prior to shipment.

[Note: Appropriate precautions should be taken both by the exporting country *and the* importing country *to ensure that the pigs are transported directly from the* place of shipment *to the* abattoir *for immediate* slaughter.*]*

Article 8.2.11.

Recommendations for importation from AD free countries or zones

for wild swine

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of AD on the day of shipment;

2. were captured in an AD free country or *zone*;

3. have not been vaccinated against the *disease*;

4. were isolated in a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.12.

Recommendations for importation from AD free countries or zones

for semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

   a) showed no clinical sign of AD on the day of collection of the semen;

   b) were kept in an *establishment* or *artificial insemination centre* located in an AD free country or *zone* at the time of semen collection;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.6. and 4.5.

Article 8.2.13.

Recommendations for importation from AD provisionally free countries or zones

for semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

Annex XV (contd)

1. the donor *animals*:

    a) have been kept for at least 4 months prior to semen collection in an *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every 4 months;

    b) showed no clinical sign of AD on the day of collection;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.6. and 4.5.

Article 8.2.14.

Recommendations for importation from AD infected countries or zones

for semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

    a) were kept in an AD free *establishment* for at least 6 months prior to entering the *artificial insemination centre*;

    b) have been kept for at least 4 months prior to semen collection in the *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every 4 months;

    c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to or 21 days after semen collection;

    d) showed no clinical sign of AD on the day of collection;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.6. and 4.5.

Article 8.2.15.

Recommendations for importation from AD free countries or zones

for *in vivo* derived embryos of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

    a) showed no clinical sign of AD on the day of collection of the embryos;

    b) were kept in an *establishment* located in an AD free country or *zone* prior to collection;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.16.

Recommendations for importation from AD provisionally free countries or zones

for *in vivo* derived embryos of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

    a) showed no clinical sign of AD on the day of collection of the embryos;

    b) were kept in an AD free *establishment* for at least 3 months prior to collection;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.17.

Recommendations for importation from AD infected countries or zones

for *in vivo* derived embryos of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

    a) showed no clinical sign of AD on the day of collection of the embryos;

    b) were kept in an AD free *establishment* for at least 3 months prior to collection;

    c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to collection;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.18.

Recommendations for importation from AD free countries or zones

for offal (head, and thoracic and abdominal viscera) of pigs or products containing pig offal

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of offal or products containing pig offal comes from *animals* which come from *establishments* located in an AD free country or *zone*.

Article 8.2.19.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zones

for offal (head, and thoracic and abdominal viscera) of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of offal comes from *animals*:

1. which have been kept in an AD free *establishment* since birth;

Annex XV (contd)

2. which have not been in contact with *animals* from *establishments* not considered free from AD during their transport to the approved *abattoir* and therein.

Article 8.2.20.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zones

for products containing pig offal (head, and thoracic and abdominal viscera)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. either the entire consignment of offal used to prepare the products complied with the conditions referred to in Article 8.2.19.; or

2. the products have been processed to ensure the destruction of the AD virus; and

3. the necessary precautions were taken after processing to avoid contact of the products with any source of AD virus.

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Annex XVI

CHAPTER 8.3.

BLUETONGUE

EU comment

The EU could only support the proposed changes if its comments are taken into account, especially in articles 8.3.3 point 3c) and 8.3.8 point 6.

Article 8.3.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue virus (BTV) shall be 60 days.

Historically, the global BTV distribution has been confined between the latitudes of approximately 53°N and north of 34°S with a recent extension in Northern Europe.

In the absence of clinical *disease* in a country or *zone*, its BTV status should be determined by an ongoing *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Articles 8.3.16. to 8.3.21.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar *surveillance*. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV or a bluetongue *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.) in the country or *zone* not having free status supports a lesser distance.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant population of the *exporting country* or *zone*.

Article 8.3.2.

Safe ~~trade~~ commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any BTV related conditions regardless of the BTV status of the ruminant population of the *exporting country* or *zone*:

1. *milk* and *milk products*;
2. *meat* and *meat products*;
3. hides and skins;
4. wool and fibre;
5. *in vivo* derived bovine embryos and oocytes collected, processed and stored in conformity with the provisions of Chapter 4.7. except for BTV8 (under study).

Article 8.3.3.

BTV free country or zone

1. A country or a *zone* may be considered free from BTV when bluetongue is notifiable in the whole country and either:

   a) a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has demonstrated no evidence of BTV in the country or *zone* during the past 2 years; or

   b) a *surveillance* programme has demonstrated no evidence of *Culicoides* in the country or *zone*.

2. A BTV free country or *zone* in which ongoing *vector surveillance*, performed according to point 5 of Article 8.3.19., has found no evidence of *Culicoides* will not lose its free status through the importation of vaccinated, seropositive or infective *animals*, or semen or embryos/ova from infected countries or *infected zones*.

3. A BTV free country or *zone* in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the importation of vaccinated or seropositive *animals* from infected countries or *infected zones*, provided:

   a) the *animals* have been vaccinated, at least 60 days prior to dispatch, in accordance with the *Terrestrial Manual* with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and the *animals* are identified in the accompanying certification as having been vaccinated; or

   b) the *animals* are not vaccinated and, at least 60 days prior to dispatch, are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the *exporting country* or *zone*~~.~~; or

   c) the *animals* are not vaccinated and a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of at least 60 days immediately prior to dispatch and no evidence of BTV transmission has been detected.

EU comment
The EU cannot support the proposed addition of the point c) above (and 8.3.8 point 6).
This so-called "new" proposal had already been discussed in 2009 and 2010 prior to the last General Session and eventually rejected by the OIE Members. Indeed, even if it was accepted by the SCAD, the Members considered that it does not provide, far from it, the same level of security as the other points. It would be like inventing a new "free zone in an infected zone" apart from the current accepted definitions, and with by no means the same criteria. This is of course not acceptable in the perspective of a proper prevention of entry of the disease in a free zone.
The important in this point is that the individual animals introduced from an infected zone do not represent a risk, and the only way is that they are individually proven free or immunized, either naturally or by vaccination.

4. A BTV free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* as described in Article 8.3.1. in which *surveillance* is conducted in accordance with Articles 8.3.16. to 8.3.21. *Animals* within this *zone* should be subjected to continuing *surveillance*. The boundaries of this *zone* should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to BTV transmission.

Article 8.3.4.

BTV seasonally free zone

A BTV seasonally free *zone* is a part of an infected country or an *infected zone* for which for part of a year, *surveillance* demonstrates no evidence either of BTV transmission or of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to conclude either:

1. at least 28 days before the earliest date that historical data show bluetongue virus activity has recommenced; or

2. immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

A BTV seasonally free *zone* in which *surveillance* has found no evidence that *Culicoides* are present will not lose its free status through the importation of vaccinated, seropositive or infective *animals*, or semen or embryos/ova from infected countries or *infected zones*.

Article 8.3.5.

BTV infected country or zone

For the purpose of this chapter, a BTV infected country or *infected zone* is a clearly defined area where evidence of BTV has been reported during the past 2 years.

Article 8.3.6.

Recommendations for importation from BTV free countries or zones

for ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *animals* were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or

2. the *animals* were kept in a BTV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual* and remained in the BTV free country or *zone* until shipment; or

3. the *animals* were kept in a BTV free country or *zone* for at least 7 days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual*, and remained in the BTV free country or *zone* until shipment; or

4. the *animals*:

    a) were kept in a BTV free country or *zone* for at least 7 days;

    b) were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme as described in Articles 8.3.16. to 8.3.21.;

    c) were identified as having been vaccinated; and

    d) remained in the BTV free country or *zone* until shipment;

AND

5. if the *animals* were exported from a free *zone*, either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from attack from *Culicoides* at all times when transiting through an *infected zone*; or

   c) had been vaccinated in accordance with point 4 above.

Article 8.3.7.

Recommendations for importation from BTV seasonally free zones

for ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. were kept during the seasonally free period in a BTV seasonally free *zone* since birth or for at least 60 days prior to shipment; or

2. were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual*, with negative results, carried out at least 28 days after the commencement of the residence period; or

3. were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after the commencement of the residence period; or

4. were kept during the seasonally free period in a BTV seasonally free *zone* and were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. and were identified as having been vaccinated and remained in the BTV free country or *zone* until shipment;

AND

5. if the *animals* were exported from a free *zone*, either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from attack from *Culicoides* at all times when transiting through an *infected zone*; or

   c) were vaccinated in accordance with point 4 above.

Article 8.3.8.

Recommendations for importation from BTV infected countries or zones

for ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. were protected from attack from *Culicoides* in an ~~insect proof~~ *vector* protected *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

EU comment

The word "an" in the point 1 above and 2 and 3 below should be "a".

2. were protected from attack from *Culicoides* in an ~~insect proof~~ *vector* protected establishment for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, carried out at least 28 days after introduction into the ~~insect proof~~ *vector* protected establishment; or

3. were protected from attack from *Culicoides* in an ~~insect proof~~ *vector* protected establishment for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after introduction into the ~~insect proof~~ *vector* protected establishment; or

4. were vaccinated, at least 60 days before shipment, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and were identified in the accompanying certification as having been vaccinated or, if demonstrated to have antibodies, have been protected from *vectors* for at least 60 days prior to shipment; or

5. demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21.; or

6. are not vaccinated and a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of at least 60 days immediately prior to dispatch and no evidence of BTV transmission has been detected, and were protected from attack from Culicoides during transportation to the *place of shipment*.

EU comment

The EU cannot support the proposed addition of the point 6) above.

This so-called "new" proposal had already been discussed in 2009 and 2010 prior to the last General Session and eventually rejected by the OIE Members. Indeed, even if it was accepted by the SCAD, the Members considered that it does not provide, far from it, the same level of security as the other points. It would be like inventing a new "free zone in an infected zone" apart from the current accepted definitions, and with by no means the same criteria. This is of course not acceptable in the perspective of a proper prevention of entry of the disease in a free zone.

The important in this point is that the individual animals introduced from an infected zone do not represent a risk, and the only way is that they are individually proven free or immunized, either naturally or by vaccination.

Article 8.3.9.

Recommendations for importation from BTV free countries or zones

for semen of ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

   a) were kept in a BTV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after the last collection for this consignment, with negative results; or

c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.10.

Recommendations for importation from BTV seasonally free zones

for semen of ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

a) were kept during the BTV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.11.

Recommendations for importation from BTV infected countries or zones

for semen of ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

a) were protected from attack from *Culicoides* for at least 60 days before commencement of, and during, collection of the semen; or

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.12.

Recommendations for importation from BTV free countries or zones

for *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

    a) were kept in a BTV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos; or

    b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

    c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.13.

Recommendations for importation from BTV seasonally free zones

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

    a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or

    b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

    c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.14.

Recommendations for importation from BTV infected countries or zones

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

    a) were protected from attack from *Culicoides* for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or

    b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.15.

Protecting animals from *Culicoides* attack

1. Vector-protected establishment or facility

The means of protection of the *establishment* or facility should at least comprise the following:

a) double-door entry-exit system;

b) openings of the building are *vector* screened with mesh of appropriate aperture size (under study) impregnated regularly with an approved insecticide according to manufacturers' instruction;

EU comment

The points a) and b) above could be too prescriptive and it should be let to the Veterinary Services to decide the actual physical and chemical vector barriers to be installed. Thus the points a) and b) should read:

"a) Appropriate physical barriers at entry and exit points and at other openings;

b) Chemical barriers through approved products applied according to manufacturers' instruction to mesh screens or other opening protection;"

Moreover, even if the use of insecticides is a tool to prevent the vectors, its activity and environmental consequences should be carefully evaluated. The use of insecticide on mesh is useful to increase the level of insect protection but it must be evaluated (frequency, quantity, type of substance) in the light of the volume of the room, the number of animals present and the air circulation. Indeed, no manufacturers' instructions exist for *Culicoides*, due to the absence of insecticides patented against *Culicoides*.

c) *vector* surveillance and control within and around the building;

EU comment

Vector surveillance within and outside stables is the key element for constantly verify the efficacy of the protection measures. However *Culicoides* control is a very difficult task and, although some general recommendations may be given, no specific measures have proven effective in the past.

d) measures to limit breeding sites for *vectors* in vicinity of the *establishment* or facility;

e) Standard Operating Procedure, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of horses to the place of *loading*.

EU comment

In the paragraph above, the word "horses" should be replaced by "animals".

2. During transportation

When transporting *animals* through BTV infected countries or *infected zones*, *Veterinary Authorities* should require strategies to protect *animals* from attack from *Culicoides* during transport, taking into account the local ecology of the *vector*.

Potential *risk management* strategies include:

~~1~~a) treating *animals* with insect repellents prior to and during transportation;

~~2~~b) *loading*, transporting and *unloading animals* at times of low *vector* activity (i.e. bright sunshine, low temperature);

~~3~~c) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the *animals* are held behind insect proof netting;

~~4~~d) darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shadecloth;

~~5~~e) *surveillance* for *vectors* at common stopping and offloading points to gain information on seasonal variations;

~~6~~f) using historical information and/or information from appropriately verified and validated BTV epidemiological models to identify low risk ports and transport routes.

Article 8.3.16.

Surveillance: introduction

Articles 8.3.16. to 8.3.21. define the principles and provide a guide on the *surveillance* for BT complementary to Chapter 1.4. and for *vectors* complementary to Chapter 1.5., applicable to Members seeking to determine their BT status. This may be for the entire country or *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of BT status is also provided.

BT is a *vector*-borne infection transmitted by different species of *Culicoides* insects in a range of ecosystems. An important component of BT epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for BT should focus on transmission in domestic ruminants.

The impact and epidemiology of BT differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. It is incumbent upon Members to provide scientific data that explain the epidemiology of BT in the region concerned and adapt the *surveillance* strategies for defining their infection status (free, seasonally free or infected country or *zone*) to the local conditions. There is considerable latitude available to Members to justify their infection status at an acceptable level of confidence.

Surveillance for BT should be in the form of a continuing programme.

Article 8.3.17.

Surveillance: case definition

For the purposes of *surveillance*, a *case* refers to an *animal* infected with BT virus (BTV).

For the purposes of *international trade*, a distinction should be made between a *case* as defined below and an *animal* that is potentially infectious to *vectors*. The conditions for trade are defined in Articles 8.3.1. to 8.3.15. of this chapter.

The purpose of *surveillance* is the detection of virus circulation in a country or *zone* and not determination of the status of an individual *animal* or *herds*. *Surveillance* deals not only with the occurrence of clinical signs caused by BTV, but also with the evidence of *infection* with BTV in the absence of clinical signs.

The following defines the occurrence of BTV infection:

1. BTV has been isolated and identified as such from an *animal* or a product derived from that *animal*, or

2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of BTV has been identified in samples from one or more *animals* showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with BTV, or

3. antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination have been identified in one or more *animals* that either show clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or give cause for suspicion of previous association or contact with BTV.

Article 8.3.18.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect *cases* of BT to a *laboratory* for BT diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2. The BT *surveillance* programme should:

   a) in a country/*zone* free or seasonally free, include an early warning system for reporting suspicious *cases*. Farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, should report promptly any suspicion of BT to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *Veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is BTV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of BT should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*;

   b) conduct random or targeted serological and virological *surveillance* appropriate to the infection status of the country or *zone*.

Generally, the conditions to prevent exposure of susceptible *animals* to BTV infected *vectors* will be difficult to apply. However, under specific situations, in establishments such as *artificial insemination centres* or *quarantine stations* exposure to *vectors* may be preventable. The testing requirements for *animals* kept in these facilities are described in Articles 8.3.11. and 8.3.14.

Article 8.3.19.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country or *zone*. Active and passive *surveillance* for BTV infection should be

ongoing. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the infection status of the country or *zone*.

The strategy employed may be based on *surveillance* using randomised sampling that would demonstrate the absence of BTV infection at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random *surveillance* is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results may be followed up with virological methods as appropriate.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods may be used concurrently to define the BTV status of targeted populations.

A Member should justify the *surveillance* strategy chosen as being adequate to detect the presence of BTV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

In vaccinated populations, serological and virological *surveillance* is necessary to detect the BTV types circulating to ensure that all circulating types are included in the vaccination programme.

If a Member wishes to declare freedom from BTV infection in a specific *zone*, the design of the *surveillance* strategy would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease/infection* are technically well defined. The design of *surveillance* programmes to prove the absence of BTV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

   Clinical *surveillance* aims at the detection of clinical signs of BT at the *flock/herd* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

   BT suspects detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

An active programme of *surveillance* of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested depends on the epidemiology of BTV infection, and the species available, in the local area. Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

Surveillance may include serological surveys, for example *abattoir* surveys, the use of cattle as sentinel *animals* (which should be individually identifiable), or a combination of methods. *Surveillance* may also be conducted by sampling and testing of bulk milk using an ELISA, as prescribed in the *Terrestrial Manual*.

The objective of serological *surveillance* is to detect evidence of BTV circulation. Samples should be examined for antibodies against BTV using tests prescribed in the *Terrestrial Manual*. Positive BTV antibody tests results can have four possible causes:

a) natural *infection* with BTV,

b) vaccination against BTV,

c) maternal antibodies,

d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for BTV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of BTV infection should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no BTV infection is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the *animals* being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of BTV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable to select *herds* and/or *animals* for testing.

A *protection zone* within a free country or *zone* should separate it from a potentially infected country or *infected zone*. Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with a potentially infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors.

Serological *surveillance* in *infected zones* will identify changes in the boundary of the zone, and can also be used to identify the BTV types circulating. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected *animals* is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* using tests described in the *Terrestrial Manual* can be conducted:

a) to identify virus circulation in at risk populations,

b) to confirm clinically suspect *cases*,

c) to follow up positive serological results,

d) to better characterize the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel *animals* are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for BTV *surveillance*. They comprise groups of unexposed *animals* managed at fixed locations and sampled regularly to detect new BTV *infections*.

The primary purpose of a sentinel animal programme is to detect BTV infections occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of *infected zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use *animals* of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of BTV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting BTV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise *animals* selected to be of similar age and susceptibility to BTV infection. Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that BTV *infections* are not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on BTVs circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of *vector surveillance* is to determine areas of different levels of risk and local details of seasonality by determining the various *vector* species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread. Long term *surveillance* can also be used to assess *vector* suppression measures.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminant *animals*.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and type of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel *animals* is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector* infection rates mean that such detections can be rare. Other *surveillance* strategies (e.g. the use of sentinel *animals* of domestic ruminants) are preferred to detect virus circulation.

Article 8.3.20.

Documentation of BTV infection free status

1. Members declaring freedom from BTV infection for the country or zone: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring freedom from BTV infection for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter, to demonstrate absence of BTV infection during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of BTV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* should be targeted to non-vaccinated *animals*. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in cattle.

2. Additional requirements for countries or zones that practise vaccination

Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of BTV *infection* in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subpopulations.

In countries or *zones* that practise vaccination, there is a need to perform virological and serological tests to ensure the absence of virus circulation. These tests should be performed on non-vaccinated subpopulations or on sentinels. The tests have to be repeated at appropriate intervals according to the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

Article 8.3.21.

The use and interpretation of serological and virus detection tests

1. Serological testing

Ruminants infected with BTV produce antibodies to structural and non-structural viral proteins, as do *animals* vaccinated with current modified live virus vaccines. Antibodies to the BTV serogroup antigen are detected with high sensitivity and specificity by competitive ELISA (c-ELISA) and to a lesser extent by AGID as described in the *Terrestrial Manual*. Positive c-ELISA results can be confirmed by neutralization assay to identify the infecting serotype(s); however, BTV infected ruminants can produce neutralizing antibodies to serotypes of BTV other than those to which they were exposed (false positive results), especially if they have been infected with multiple serotypes.

2. Virus detection

The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV *infection*, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of PCR assays:

a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active *infection* of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.

b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect *vectors* or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

It is essential that BTV isolates are sent regularly to the OIE Reference Laboratories for genetic and antigenic characterization.

Fig. 1. Application of laboratory tests in serological surveillance

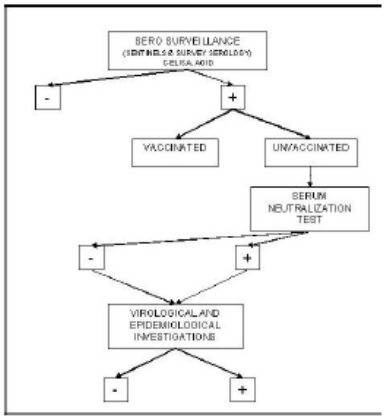
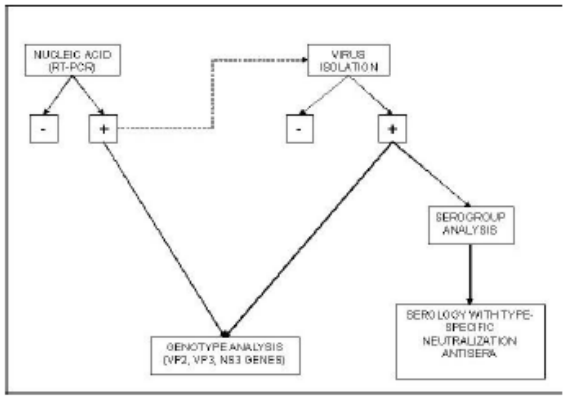


Fig. 2. Application of laboratory tests in virological surveillance



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Annex XVII

CHAPTER 8.5.

FOOT AND MOUTH DISEASE

EU comment

The EU can support the proposed changes, except the merging of article 22 to 24, to which it is opposed, and has some comments.

Article 8.5.1.

Introduction

For the purposes of the *Terrestrial Code*, the *incubation period* for foot and mouth disease (FMD) shall be 14 days.

For the purposes of this Chapter, ruminants include *animals* of the family of Camelidae (except *Camelus dromedarius*).

For the purposes of this Chapter, a *case* includes an *animal* infected with FMD virus (FMDV).

~~For the purposes of *international trade*, t~~This Chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV in the absence of clinical signs.

The following defines the occurrence of FMDV infection:

1. FMDV has been isolated and identified as such from an *animal* or a product derived from that *animal*; or

2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more *animals*, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more *animals* showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.5.2.

FMD free country where vaccination is not practised

Susceptible *animals* in the FMD free country where vaccination is not practised should be protected from neighbouring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the existing list of FMD free countries where vaccination is not practised, a Member should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE stating that:

   a) there has been no *outbreak* of FMD during the past 12 months;

b) no evidence of FMDV infection has been found during the past 12 months;

c) no vaccination against FMD has been carried out during the past 12 months;

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d) no vaccinated *animal* has been introduced since the cessation of vaccination;

3. supply documented evidence that:

a) *surveillance* for FMD and FMDV infection in accordance with Articles 8.5.42. to 8.5.48. is in operation;

b) regulatory measures for the early detection, prevention and control of FMD have been implemented.

4. describe in detail the boundaries and measures of a *protection zone*, if applicable.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

Article 8.5.3.

FMD free country where vaccination is practised

Susceptible *animals* in the FMD free country where vaccination is practised should be protected from neighbouring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free countries where vaccination is practised, a Member should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE stating that:

a) there has been no *outbreak* of FMD during the past 2 years;

b) no evidence of FMDV circulation has been found during the past 12 months;

3. supply documented evidence that:

a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.42. to 8.5.48. is in operation;

b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

c) routine vaccination is carried out for the purpose of the prevention of FMD;

d) the vaccine used complies with the standards described in the *Terrestrial Manual* and is appropriate for the strains of virus currently circulating;

4. describe in detail the boundaries and measures of a *protection zone*, if applicable.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in point 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that meets the requirements of a FMD free country where vaccination is practised wishes to change its status to FMD free country where vaccination is not practised, the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred during that period.

Article 8.5.4.

FMD free zone where vaccination is not practised

An FMD free *zone* where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* should be protected from the rest of the country and from neighbouring countries if they are of a different *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free *zones* where vaccination is not practised, a Member should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE stating that within the proposed FMD free *zone*:

    a) there has been no *outbreak* of FMD during the past 12 months;

    b) no evidence of FMDV infection has been found during the past 12 months;

    c) no vaccination against FMD has been carried out during the past 12 months;

    d) no vaccinated *animal* has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.10.;

3. supply documented evidence that:

    a) *surveillance* for FMD and FMDV infection in accordance with Articles 8.5.42. to 8.5.48. is in operation;

    b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

4. describe in detail and supply documented evidence that these are properly implemented and supervised:

    a) the boundaries of the proposed FMD free *zone*,

    b) the boundaries and measures of a *protection zone*, if applicable,

    c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD~~V~~ free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).

The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is not practised only after the submitted evidence has been accepted by the OIE.

The information required in points 2, 3 and 4b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 b)-c) should be reported to the OIE according to the requirements in Chapter 1.1.

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Article 8.5.5.

FMD free zone where vaccination is practised

An FMD free *zone* where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* where vaccination is practised should be protected from neighbouring countries or *zones* if they are of a lesser *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free *zones* where vaccination is practised, a Member should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE that within the proposed FMD free *zone*;

    a) there has been no *outbreak* of FMD for the past 2 years;

    b) no evidence of FMDV circulation has been found during the past 12 months;

3. supply documented evidence that:

    a) *surveillance* for FMD and FMDV ~~infection~~ circulation in accordance with Articles 8.5.42. to 8.5.48. is in operation;

    b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

    c) routine vaccination is carried out for the purpose of the prevention of FMD;

    d) the vaccine used complies with the standards described in the *Terrestrial Manual* and is appropriate for the strains of virus currently circulating;

4. describe in detail and supply documented evidence that these are properly implemented and supervised:

    a) the boundaries of the proposed FMD free *zone*,

    b) the boundaries and measures of a *protection zone*, if applicable,

    c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).

The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3 b) and 4 b)-c) should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that has a *zone* which meets the requirements of a FMD free *zone* where vaccination is practised wishes to change the status of the *zone* to FMD free *zone* where vaccination is not practised, the status of this *zone* remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred in the said *zone* during that period.

Article 8.5.6.

FMD free compartment

A FMD free *compartment* can be established in either a FMD free country or *zone* or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Susceptible *animals* in the FMD free *compartment* should be separated from any other susceptible *animals* by the application of an effective biosecurity management system.

A Member wishing to establish a FMD free *compartment* should:

1. have a record of regular and prompt animal disease reporting and if not FMD free, have an official control programme and a *surveillance* system for FMD in place according to Articles 8.5.42. to 8.5.44. that allows an accurate knowledge of the prevalence of FMD in the country or *zone*;

2. declare for the FMD free *compartment* that:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV infection has been found during the past 12 months;

   c) vaccination against FMD is prohibited;

   d) no *animal* vaccinated against FMD within the past 12 months is in the *compartment*;

   e) *animals*, semen and embryos should only enter the *compartment* in accordance with relevant Articles in this chapter;

   f) documented evidence shows that *surveillance* in accordance with Articles 8.5.42. to 8.5.48. is in operation for FMD and FMDV infection;

   g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3. describe in detail the animal subpopulation in the *compartment* and the biosecurity plan for FMD and FMDV infection.

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no *outbreak* of FMD has occurred within the *zone* in which the *compartment* is situated, during the last 3 months.

Article 8.5.7.

FMD infected country or zone

For the purpose of this Chapter,

An FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.

An FMD *infected zone* is a *zone* that does not fulfil the requirements to qualify as either an FMD free *zone* where vaccination is not practised or an FMD free *zone* where vaccination is practised.

EU comment
The word "infected" above should not be in italics.

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Article 8.5.7bis.

OIE endorsed national FMD control programme

Countries may apply for endorsement of their national FMD control programme when they have implemented measures that could potentially lead to OIE official recognition of FMD free status.

For a Member's national FMD control programme to be endorsed by the OIE, the Member should:

1. have submitted documented evidence on the capacity of the veterinary services to control FMD. This evidence can be provided by countries following the OIE PVS pathway to identify gaps and the strategies to strengthen the veterinary services to sustainably control FMD;

2. submit documentation indicating that the national FMD control programme consistent with the recommendation of Chapter 8.5. is applicable to the entire territory or *zone*;

3. have a record of regular and prompt animal disease reporting according to the requirements in Chapter 1.1.;

4. have submitted a dossier on the epidemiology of FMD in the country describing the following:

   a) the general epidemiology of FMD in the country highlighting the current knowledge and gaps,

   b) the measures to prevent introduction of *infection* from neighbouring countries;

   c) the prevailing livestock production systems and movement patterns of FMD susceptible *animals* and their products within and into the country;

5. have submitted a detailed plan on the approach to control and eventually eradicate FMD in the country or *zone* including:

   a) the timeline of the control programme,

   b) the performance indicators to assess the efficacy of the control measures implemented in the framework of the programme;

6. have submitted evidence that FMD *surveillance*, taking into account provisions in Chapter 1.4. of the *Terrestrial Code* and the provisions on *surveillance* of this Chapter, is in place;

7. have diagnostic capability and procedures which include regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the *Terrestrial Manual*;

8. where vaccination is practised as a part of national FMD control programme, provide legislation making vaccination compulsory on selected populations;

9. if applicable, provide detailed information on vaccination campaigns in particular on:

   a) target populations for vaccination,

   b) monitoring of vaccination coverage, including serological monitoring of population immunity,

   c) technical specification of the vaccines used and description of the licensing procedures in place,

   d) the proposed timeline for the transition to the use of vaccines, fully compliant with the standards and methods described in the OIE *Terrestrial Manual;*

10. provide an Emergency Preparedness and Response Plan which is implemented in case of *outbreaks*.

The Member's national programme will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the FMD control programme and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the national FMD control programme if there is evidence of:

11. a decreased capability of the veterinary services, or

12. an uncontrolled increase in incidence of FMD.

Article 8.5.8.

Establishment of a containment zone within an FMD free country or zone

In the event of limited *outbreaks* within an FMD free country or *zone*, including within a *protection zone*, with or without vaccination, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*. For this to be achieved and for the Member to take full advantage of this process, the *Veterinary Authority* should ~~provide~~ submit documented evidence as soon as possible to the OIE that:

1. the *outbreaks* are limited based on the following factors:

   a) immediately on suspicion, a rapid response including notification has been made;

   b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;

   c) epidemiological investigation (trace-back, trace-forward) has been completed;

   d) the *infection* has been confirmed;

   e) the primary *outbreak* has been identified and investigations on the likely source of the *outbreak* ~~has been identified~~ have been carried out;

   f) all *cases* have been shown to be epidemiologically linked;

   g) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.5.1. after the stamping-out of the last detected *case* is completed;

2. a *stamping-out policy* has been applied;

3. the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*;

4. increased passive and targeted *surveillance* in accordance with Articles 8.5.42. to 8.5.48. in the rest of the country or *zone* has been carried out and has not detected any evidence of *infection*;

5. animal health measures that effectively prevent the spread of the FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place;

6. ongoing *surveillance* in the *containment zone* is in place.

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The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated irrespective of the provisions of Article 8.5.9., once the *containment zone* is clearly established, by complying with points 1 to 6 above. The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for *international trade* can be shown to have originated outside the *containment zone*.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.5.9.

Article 8.5.9.

Recovery of free status

1. When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where vaccination is not practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where vaccination is not practised:

   a) 3 months after the last *case* where a *stamping-out policy* and serological *surveillance* are applied in accordance with Articles 8.5.42. to 8.5.48.; or

   b) 3 months after the *slaughter* of all vaccinated *animals* where a *stamping-out policy*, emergency vaccination and serological *surveillance* are applied in accordance with Articles 8.5.42. to 8.5.48.; or

   c) 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping-out policy*, emergency vaccination not followed by the slaughtering of all vaccinated *animals*, and serological *surveillance* are applied in accordance with Articles 8.5.42. to 8.5.48., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population.

   Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. or 8.5.4. applies.

2. When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where vaccination is practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where vaccination is practised:

   a) 6 months after the last *case* where a *stamping-out policy*, emergency vaccination and serological *surveillance* in accordance with Articles 8.5.42. to 8.5.48. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or

   b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological *surveillance* in accordance with Articles 8.5.42. to 8.5.48. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

3. When a FMD *outbreak* or FMDV infection occurs in a FMD free *compartment*, Article 8.5.6. applies.

Article 8.5.10.

Direct ~~T~~transfer ~~directly to slaughter~~ of FMD susceptible animals from an infected zone for slaughter ~~to~~ in a free zone (where vaccination either is or is not practised) ~~within a country~~

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *infected zone* if ~~moved~~ transported ~~by mechanised transport~~ directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1. no FMD susceptible *animal* has been introduced into the *establishment* of origin and no *animal* in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2. the *animals* were kept in the *establishment* of origin for at least 3 months prior to movement;

3. FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for at least 3 months prior to movement;

4. the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;

5. such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *infected zone*;

6. *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be treated according to Article 8.5.25. or Article 8.5.26. Other products obtained from the *animals* and any products coming into contact with them should be considered infected, and treated in such a way as to destroy any residual virus in accordance with Articles 8.5.34. to 8.5.41.

Animals moved into a free *zone* for other purposes should be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 8.5.14.

Article 8.5.11.

Transfer directly to slaughter of FMD susceptible animals from a containment zone to a free zone (where vaccination either is or is not practised) within a country

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *containment zone* if moved by mechanised transport directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1. the *containment zone* has been officially established according to the requirements in Article 8.5.8.;

2. the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the establishment of origin to the *abattoir* without coming into contact with other susceptible *animals*;

3. such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *containment zone*;

4. *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be treated according to point 2 of Article 8.5.25. or Article 8.5.26. Other products obtained from the *animals* and any products coming into contact with them should be treated in such a way as to destroy any residual virus in accordance with Articles 8.5.34. to 8.5.41.

Article 8.5.12.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments

for FMD susceptible animals

Annex XVII (contd)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of FMD on the day of shipment;

2. were kept since birth or for at least the past 3 months in a FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*;

3. have not been vaccinated;

4. if transiting an *infected zone*, were not exposed to any source of FMDV infection during transportation to the *place of shipment*.

Article 8.5.13.

Recommendations for importation from FMD free countries or zones where vaccination is practised

for domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of FMD on the day of shipment;

2. were kept in an FMD free country or *zone* since birth or for at least the past 3 months; and

3. have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus, when destined to an FMD free country or *zone* where vaccination is not practised;

4. if transiting an *infected zone*, were not exposed to any source of FMDV infection during transportation to the *place of shipment*.

Article 8.5.14.

Recommendations for importation from FMD infected countries or zones

for domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of FMD on the day of shipment;

2. were kept in the *establishment* of origin since birth, or

   a) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country*, or

   b) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country*,

   and that FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for the relevant period as defined in points a) and b) above; and

3. were isolated in an *establishment* for the 30 days prior to shipment, and all *animals* in isolation were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *establishment* during that period; or

4. were kept in a *quarantine station* for the 30 days prior to shipment, all *animals* in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *quarantine station* during that period;

5. were not exposed to any source of FMDV *infection* during their transportation from the *quarantine station* to the *place of shipment*.

Article 8.5.15.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments

for fresh semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen;

   b) were kept for at least 3 months prior to collection in a FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.16.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments

for frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least 3 months prior to collection in an FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.17.

Recommendations for importation from FMD free countries or zones where vaccination is practised

for semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

Annex XVII (contd)

b) were kept for at least 3 months prior to collection in a FMD free country or *zone*;

c) if destined to an FMD free country or *zone* where vaccination is not practised:

i) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

ii) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;

2. no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;

3. the semen:

a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

b) was stored in the country of origin for a period of at least one month following collection, and during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.18.

Recommendations for importation from FMD infected countries or zones

for semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

a) showed no clinical sign of FMD on the day of collection of the semen;

b) were kept in an *establishment* where no *animal* had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;

c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

d) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;

2. no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;

3. the semen:

a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

b) was subjected, with negative results, to a test for FMDV *infection* if the donor *animal* has been vaccinated within the 12 months prior to collection;

c) was stored in the country of origin for a period of at least one month following collection, and during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.19.

Recommendations for the importation of *in vivo* derived embryos of cattle

Irrespective of the FMD status of the *exporting country*, *zone* or *compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.5.20.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments

for *in vitro* produced embryos of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept at the time of collection in a FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*;

2. fertilisation was achieved with semen meeting the conditions referred to in Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18., as relevant;

3. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.21.

Recommendations for importation from FMD free countries or zones where vaccination is practised

for *in vitro* produced embryos of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept for at least 3 months prior to collection in a FMD free country or *zone* where vaccination is practised;

   c) if destined for an FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*:

      i) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or

      ii) had been vaccinated at least twice, with the last vaccination not less than one month and not more than 12 months prior to collection;

2. no other *animal* present in the *establishment* has been vaccinated within the month prior to collection;

3. fertilization was achieved with semen meeting the conditions referred to in Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18., as relevant;

4. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.22.

Recommendations for importation from FMD free countries or zones where vaccination is or is not practised or from FMD free compartments

for fresh meat or meat products of FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:

EU comment

The words "entire consignment of" above are superfluous and should be deleted. On the certificate, which always refers to one specific consignment, the words "the meat" are sufficient and self explanatory.

1. have been kept in the FMD free country or *zone* where vaccination is or is not practised, or in a FMD free *compartment*, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;

2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

EU comment

The EU supports the addition of "meat products" in the article 8.5.22 but cannot support the proposed merging of articles 8.5.22, 23 and 24.

Indeed, the level of risk for countries and zones free with vaccination is higher than without. That is why the feet, head and viscera of cattle and buffaloes should be excluded from fresh meat coming from those countries or zones.

Moreover, in article 8.5.23, the second line should read

"for fresh meat and meat products of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

And, as already expressed in former EU comments, there should be additional mitigation measures such as:

"3. fresh meat comes from deboned carcasses:

a) from which the major lymphatic nodes have been removed;

b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi."

~~Article 8.5.23.~~

~~**Recommendations for importation from FMD free countries or zones where vaccination is practised**~~

~~for fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:~~

~~1. have been kept in the FMD free country or *zone* where vaccination is practised, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;~~

~~2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.~~

~~Article 8.5.24.~~

~~**Recommendations for importation from FMD free countries or zones where vaccination is practised**~~

~~for fresh meat or meat products of pigs and ruminants other than cattle and buffaloes~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:~~

~~1. have been kept in the FMD free country or *zone* where vaccination is practised, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;~~

~~2. have been slaughtered in an approved *abattoir* and have been subjected to ante mortem and post mortem inspections for FMD with favourable results.~~

Article 8.5.25.

Recommendations for importation from FMD infected countries or zones, where ~~a~~ ~~an official~~ national FMD control programme ~~exists~~, involving compulsory systematic vaccination of cattle , has been endorsed by the OIE

for fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat*:

1. comes from *animals* which:

   a) have remained in the *exporting country* for at least 3 months prior to *slaughter*;

   b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;

   c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to *slaughter*;

   d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;

   e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other *animals* which do not fulfil the required conditions for export;

   f) have been slaughtered in an approved *abattoir*:

i) which is officially designated for export;

ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;

2. comes from deboned carcasses:

a) from which the major lymphatic nodes have been removed;

b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 8.5.26.

Recommendations for importation from FMD infected countries or zones

for meat products of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the entire consignment of *meat* comes from *animals* which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results;

2. the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.34.;

3. the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 8.5.27.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised) or FMD free compartments

for milk and milk products intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in a FMD free country, *zone* or *compartment*, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.

EU comment

The article 8.5.27 is not clear enough and could lead to confusion. Indeed, it clearly does not apply to milk for animal consumption, but could nevertheless be interpreted as such, because there is no other article covering this situation, where the risk would be higher.

Thus, it should be expressly stated that for the use in animal feed, if the products come from a country or zone free with vaccination, they should have been submitted to a heat treatment.

Thus the EU proposes to add a new article as follows:

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised) or FMD free compartments

for milk and milk products intended for use in animal feeding

Veterinary Authorities **should require the presentation of an** ***international veterinary certificate*** **attesting that these products come from** ***animals*** **which have been kept in a FMD free country or** ***zone*** **where vaccination is not practised or a free compartment, or that the products have been processed in conformity with the procedures referred to in article 8.5.39.**

Article 8.5.28.

Recommendations for importation from FMD infected countries or zones where an official control programme exists

EU comment

The same modification should be made to the title of the article 8.5.28 as in article 8.5.25. The title should read:

"Recommendations for importation from FMD infected countries or zones where a~~n official~~ national FMD control programme ~~exists~~ has been endorsed by the OIE"

for milk, cream, milk powder and milk products

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. these products:

    a) originate from *herds* or *flocks* which were not infected or suspected of being infected with FMD at the time of *milk* collection;

    b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.38. and in Article 8.5.39.;

2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 8.5.29.

Recommendations for importation from FMD infected countries

for blood and meat-meals (from domestic or wild ruminants and pigs)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

Article 8.5.30.

Recommendations for importation from FMD infected countries

for wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and pigs)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 8.5.35., 8.5.36. and 8.5.37.;

2. the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

Veterinary Authorities can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather - e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.5.31.

Recommendations for importation from FMD infected countries or zones

for straw and forage

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these *commodities*:

1. are free of grossly identifiable contamination with material of animal origin;

2. have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:

   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least 10 minutes,

   b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least 8 hours and at a minimum temperature of 19°C;

OR

3. have been kept in bond for at least 3 months (under study) before being released for export.

Article 8.5.32.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

for skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from *animals* that have been killed in such a country or *zone*, or which have been imported from a country or *zone* free of FMD (where vaccination either is or is not practised).

Article 8.5.33.

Recommendations for importation from FMD infected countries or zones

for skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 8.5.40.

Article 8.5.34.

Procedures for the inactivation of the FMD virus in meat

For the inactivation of viruses present in *meat*, one of the following procedures should be used:

1. Canning

   Meat is subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

   Meat, previously deboned and defatted, shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

   After cooking, it shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

   When *rigor mortis* is complete, the *meat* must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

   'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

Article 8.5.35.

Procedures for the inactivation of the FMD virus in wool and hair

For the inactivation of viruses present in wool and hair for industrial use, one of the following procedures should be used:

1. industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);

2. chemical depilation by means of slaked lime or sodium sulphide;

3. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;

4. industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C;

5. storage of wool at 18°C for 4 weeks, or 4°C for 4 months, or 37°C for 8 days.

Article 8.5.36.

Procedures for the inactivation of the FMD virus in bristles

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

1. boiling for at least one hour;

2. immersion for at least 24 hours in a 1% solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 8.5.37.

Procedures for the inactivation of the FMD virus in raw hides and skins

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2% sodium carbonate.

Article 8.5.38.

Procedures for the inactivation of the FMD virus in milk and cream for human consumption

For the inactivation of viruses present in *milk* and cream for human consumption, one of the following procedures should be used:

1. a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or

2. if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]), or

3. if the milk has a pH of 7.0 or over, the HTST process applied twice.

Article 8.5.39.

Procedures for the inactivation of the FMD virus in milk for animal consumption

For the inactivation of viruses present in *milk* for animal consumption, one of the following procedures should be used:

1. the HTST process applied twice;

2. HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with dessication;

3. UHT combined with another physical treatment referred to in point 2 above.

Article 8.5.40.

Procedures for the inactivation of the FMD virus in skins and trophies from wild animals susceptible to the disease

For the inactivation of viruses present in skins and trophies from wild *animals* susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

Annex XVII (contd)

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;

2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3. soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate - Na2CO3) maintained at pH 11.5 or above for at least 48 hours;

4. soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5. in the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate - Na2CO3).

Article 8.5.41.

Procedures for the inactivation of the FMD virus in casings of ruminants and pigs

For the inactivation of viruses present in casings of ruminants and pigs, the following procedures should be used:

salting for at least 30 days either with dry salt (NaCl) or with saturated brine (Aw < 0.80), or with phosphate salts/sodium chloride mixture,and kept at room temperature of about 20°C during this entire period.

Article 8.5.42.

Surveillance: introduction

Articles 8.5.42. to 8.5.48. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Members seeking establishment of freedom from FMD, either with or without the use of vaccination. Guidance is provided for Members seeking reestablishment of freedom from FMD for the entire country or for a *zone*, either with or without vaccination, or a *compartment*, following an *outbreak* and for the maintenance of FMD status.

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMD virus (FMDV) should differ significantly from an application designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*. It is incumbent upon the Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that the absence of FMDV *infection* (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.

Surveillance for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV *infection*/circulation.

For the purposes of this Chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.

Article 8.5.43.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect *cases* of FMD to a *laboratory* for FMD diagnoses as described in the *Terrestrial Manual*.

2. The FMD *surveillance* programme should:

    a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect *cases* of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control;

b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of *animals*, such as those adjacent to an FMD infected country or *infected zone* (for example, bordering a game park in which infected wildlife are present).

An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV *infection*/circulation should, in consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 8.5.44.

Surveillance strategies

1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species within the country, *zone* or *compartment*.

The design of *surveillance* programmes to prove the absence of FMDV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The Member should justify the *surveillance* strategy chosen as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member wishes to apply for recognition of a specific *zone* within the country as being free from FMDV *infection*/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of *animals* in the target population.

Irrespective of the testing system employed, *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection*/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *herds* which may be epidemiologically linked to it.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of FMD by close physical examination of susceptible *animals*. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. It may be able to provide a high level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible *animals* is examined.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.

A number of issues must be considered in clinical *surveillance* for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

Identification of clinical *cases* is fundamental to FMD *surveillance*. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such *animals*. It is essential that FMDV isolates are sent regularly to the regional reference *laboratory* for genetic and antigenic characterization.

3. Virological surveillance

Virological *surveillance* using tests described in the *Terrestrial Manual* should be conducted:

a) to monitor at risk populations;

b) to confirm clinically suspect *cases*;

c) to follow up positive serological results;

d) to test "normal" daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological *surveillance* aims at detecting antibodies against FMDV. Positive FMDV antibody test results can have four possible causes:

a) natural *infection* with FMDV;

b) vaccination against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);

d) heterophile (cross) reactions.

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).

It may be possible to use serum collected for other survey purposes for FMD *surveillance*. However, the principles of survey design described in this Chapter and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV *infection* is not present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.5.45.

Members applying for recognition of freedom from FMD for the whole country or a zone where vaccination is not practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of FMD freedom for the country or a *zone* where vaccination is not practised should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Chapter, to demonstrate absence of FMDV *infection*, during the preceding 12 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Article 8.5.46.

Members applying for recognition of freedom from FMD for the whole country or a zone where vaccination is practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of country or *zone* freedom from FMD with vaccination should show evidence of an effective *surveillance* programme planned and implemented according to general conditions and methods in this Chapter. Absence of clinical *disease* in the country or *zone* for the past 2 years should be demonstrated. Furthermore, *surveillance* should demonstrate that FMDV has not been circulating in any susceptible population during the past 12 months. This will require serological *surveillance* incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of *herd* immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should~~, in general,~~ be for ~~to vaccinate~~ at least 80% of each vaccinated ~~the susceptible~~ population to be immunised. The vaccine must comply with the *Terrestrial Manual*. Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

Evidence to show the effectiveness of the vaccination programme should be provided.

Article 8.5.47.

Members re-applying for recognition of freedom from FMD for the whole country or a zone where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a country re-applying for country or *zone* freedom from FMD where vaccination is practised or not practised should show evidence of an active *surveillance* programme for FMD as well as absence of FMDV *infection*/circulation. This will require serological *surveillance* incorporating, in the case of a country or a *zone* practising vaccination, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*.

Four strategies are recognised by the OIE in a programme to eradicate FMDV *infection* following an *outbreak*:

1. *slaughter* of all clinically affected and in-contact susceptible *animals*;

2. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, with subsequent *slaughter* of vaccinated *animals*;

3. *slaughter* of all clinically affected and in-contact susceptible animals and vaccination of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals*;

4. vaccination used without *slaughter* of affected *animals* or subsequent *slaughter* of vaccinated *animals*.

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 8.5.9.

In all circumstances, a Member re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active *surveillance* programme implemented according to general conditions and methods in this Chapter.

Article 8.5.48.

The use and interpretation of serological tests (see Figure 1)

The recommended serological tests for FMD *surveillance* are described in the *Terrestrial Manual*.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT). The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In contrast to SP tests, NSP tests can detect antibodies to all serotypes of FMD virus. *Animals* vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, but in some, the titre may be lower than that found in infected *animals* that have not been vaccinated. Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD *surveillance*. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV *infection*/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical *surveillance*. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results.

In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However, NSP antibody tests should be used to monitor for FMDV *infection*/circulation. NSP-ELISAs may be used for screening sera for evidence of *infection*/circulation irrespective of the vaccination status of the *animal*. All *herds* with seropositive reactors should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of FMDV *infection*/circulation for each positive *herd*. Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.

Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.

1. The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination

   Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor *animal* at hand, of susceptible *animals* of the same *epidemiological unit* and of susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal*. If the follow-up investigations provide no evidence for FMDV *infection*, the reactor *animal* shall be classified as FMD negative. In all other cases, including the absence of such follow-up investigations, the reactor *animal* should be classified as FMD positive.

2. The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free status with vaccination

   In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on FMD vaccinated populations.

   The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

   It is suggested that in the primary sampling units where at least one *animal* reacts positive to the NSP test, the following strategy(ies) should be applied:

   a. Following clinical examination, a second serum sample should be taken from the *animals* tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. The number of *animals* with antibodies against NSP in the population at the time of retest should be statistically either equal to or less than that observed in the initial test if virus is not circulating.

      The *animals* sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all *animals* tested are individually identified. These *animals* should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

   b. Following clinical examination, serum samples should be collected from representative numbers of susceptible *animals* that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

   c. Following clinical examination, epidemiologically linked *herds* should be serologically tested and satisfactory results should be achieved if virus is not circulating.

   d. Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence.

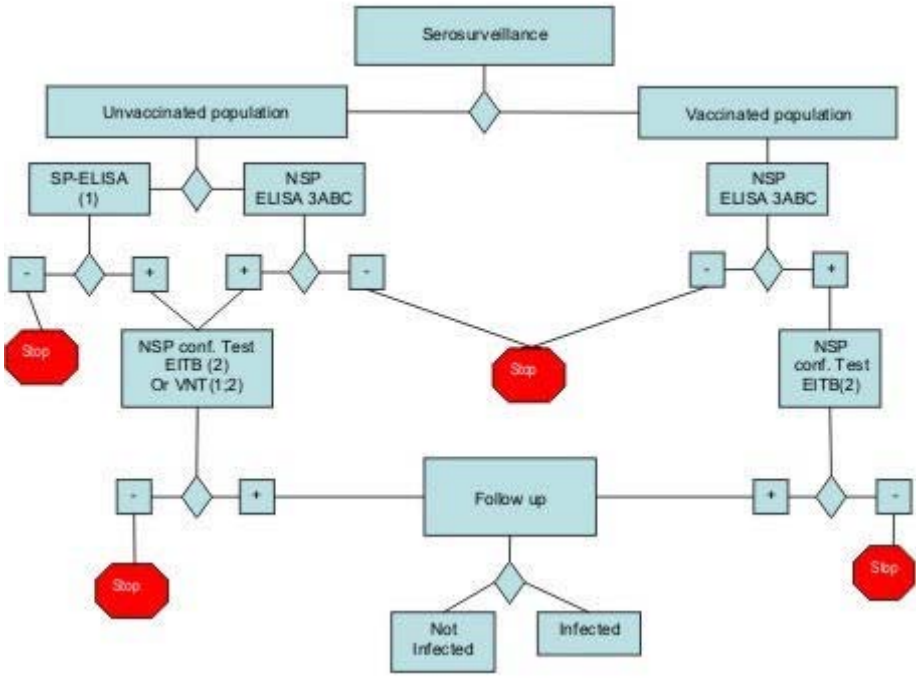
Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- characterization of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- quantification of vaccinations performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;

- control of *animal identification* and movements;
- other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

Fig. 1. ***Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys***



Key:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
EITB	Electro-immuno transfer blotting technique (Western blot for NSP antibodies of FMDV)
SP	Structural protein test
S	No evidence of FMDV

Annex XVII (contd)

CHAPTER 1.6.

STATUS FOR OIE LISTED DISEASES: PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

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Article 1.6.3.

Questionnaire on foot and mouth disease

FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED

Report of a Member which applies for recognition of status, under Chapter 8.5.
of the *Terrestrial Animal Health Code* (2010), as a FMD free country not practising vaccination

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.

   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.

   b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how the Veterinary Services supervise and control all FMD related activities. Provide maps and tables wherever possible.

   c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).

   d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

   a) History. Provide a description of the FMD history in the country, date of first detection, origin of *infection*, date of eradication (date of last *case*), types and subtypes present.

   b) Strategy. Describe how FMD was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication.

   c) Vaccines and vaccination. Was FMD vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated?

d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the FMD approved laboratories, in particular to address the following points:

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

ii) Give details of participation in inter-laboratory validation tests (ring tests).

iii) Is live virus handled?

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.5.42. to 8.5.48. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

Annex XVII (contd)

e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Are there controls in place for swill feeding to pigs containing animal products? If so provide information on the extent of the practice, and describe controls and surveillance measures.

EU comment

For consistency, this question should also be added to points 6 of the other questionnaires for FMD free countries and zones, and point 3 of the questionnaire for OIE endorsed national FMD control programme.

~~b~~c) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past two years, specifying country or *zone* of origin, species and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- *animals*,
- genetic material (semen and embryos),
- animal products,
- veterinary medicinal products (i.e. biologics).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.

b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?

c) In the event of an FMD *outbreak*:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;

iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;

iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;

v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

a) In addition to the documentary evidence that the provisions of Article 8.5.2. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

i) there has been no *outbreak* of FMD during the past 12 months;

ii) no evidence of FMDV *infection* has been found during the past 12 months;

iii) no vaccination against FMD has been carried out during the past 12 months,

b) and should confirm that since the cessation of vaccination no *animals* vaccinated against FMD have been imported.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED

Report of a Member which applies for recognition of status, under Chapter 8.5.
of the *Terrestrial Animal Health Code* (2010), as a FMD free country practising vaccination

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.

b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.

b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all FMD related activities in the country and in the *zone*. Provide maps and tables wherever possible.

c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).

d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

a) History. Provide a description of the FMD history in the country, provide date of first detection, origin of *infection*, date of eradication (date of last *case*), types and subtypes present.

b) Strategy. Describe how FMD was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication.

c) Vaccines and vaccination. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).

d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability, including vaccination data. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to and the follow-up procedures and the timeframe for obtaining results.

b) Provide an overview of the FMD approved laboratories, in particular to address the following points:

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

ii) Give details of participation in inter-laboratory validation tests (ring tests).

iii) Is live virus handled?

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.5.42. to 8.5.48. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

b) Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.5.46.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past two years, specifying country or *zone* of origin, species and volume.

Annex XVII (contd)

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- *animals*,
- genetic material (semen and embryos),
- animal products,
- veterinary medicinal products (i.e. biologics).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.

b)` Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?

c) In the event of an FMD *outbreak*:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;

iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;

iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;

v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.5.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating that there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that:

a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.42. to 8.5.48. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

b) routine vaccination is carried out for the purpose of the prevention of FMD;

c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED

Report of a Member which applies for recognition of status, under Chapter 8.5.
of the *Terrestrial Animal Health Code* (2010), as a FMD free zone not practising vaccination

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

2. Veterinary system

a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.

b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all FMD related activities in the country and in the *zone*. Provide maps and tables wherever possible.

c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).

d) Role of private veterinary profession in FMD *surveillance* and control.

Annex XVII (contd)

3. FMD eradication

a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), types and subtypes present.

b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out), provide timeframe for eradication.

c) Vaccines and vaccination. If vaccination is used in the rest of the country, what type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).

d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.5.10. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed, the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the FMD approved laboratories, in particular to address the following points:

   a) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

   b) Give details of participation in inter-laboratory validation tests (ring tests).

   c) Is live virus handled?

   d) Biosecurity measures applied.

   e) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with the provisions of Articles 8.5.42. to 8.5.48. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past 2 years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country and the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* without vaccination is situated in an FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past 2 years, specifying country or *zone* of origin, species and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

Annex XVII (contd)

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 2 years, of the quantity disposed of.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- *animals*,
- genetic material (semen and embryos),
- animal products,
- veterinary medicinal products (i.e. biologics).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.

b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?

c) In the event of an FMD *outbreak*:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;

iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;

iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;

v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.5.4. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

a) there has been no *outbreak* of FMD during the past 12 months;

b) no evidence of FMDV *infection* has been found during the past 12 months;

c) no vaccination against FMD has been carried out during the past 12 months;

d) no vaccinated animal has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.10.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

FMD FREE ZONE WHERE VACCINATION IS PRACTISED

Report of a Member which applies for recognition of status, under Chapter 8.5. of the *Terrestrial Animal Health Code* (2010), as a FMD free zone practising vaccination

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

2. Veterinary system

a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.

b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all FMD related activities in the country and in the *zone*. Provide maps and tables wherever possible.

c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).

d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), types and subtypes present.

b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out), provide timeframe for eradication.

c) Vaccines and vaccination. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme in the country and in the *zone*, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).

Annex XVII (contd)

d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability, including vaccination data. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.5.10. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed.

b) Provide an overview of the FMD approved laboratories, in particular to address the following points.

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

ii) Give details of participation in inter-laboratory validation tests (ring tests).

iii) Is live virus handled?

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with the provisions of Articles 8.5.42. to 8.5.48. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).

b) Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.5.46.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past 2 years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

d) Wildlife demographics. What susceptible species are present in the country and in the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* with vaccination is situated in an FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past 2 years, specifying the country or *zone* of origin, the species and the volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 2 years, of the quantity disposed of.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- *animals*,
- genetic material (semen and embryos),
- animal products,
- veterinary medicinal products (i.e. biologics).

Annex XVII (contd)

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.

b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?

c) In the event of an FMD *outbreak*:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;

iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;

iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;

v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.5.5. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

a) that there has been no *outbreak* of FMD for the past 2 years,

b) no evidence of FMDV circulation for the past 12 months,

c) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.42. to 8.5.48. is in operation.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

COUNTRY WITH AN OIE ENDORSED NATIONAL FMD CONTROL PROGRAMME

Report of a Member which applies for endorsement of status, under Chapter 8.5.
of the *Terrestrial Code* (2010), as a Member with a endorsed national FMD control programme.

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages

Annex XVII (contd)

1. Introduction

a) Provide a general description of geographical factors in the country and any zones, including physical, geographical and other factors that are relevant to FMD dissemination, countries or zones sharing common borders and other countries or zones that, although not adjacent, present a risk for the introduction of disease.

b) If the endorsed plan is gradually implemented to specific parts of the country, the boundaries of the zone(s) should be clearly defined, including the protection zone, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone(s).

c) Provide a general description of the livestock industry in the country and any zones.

2. Veterinary system

a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to the FMD control programme.

b) Veterinary Services. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the veterinary services supervise and control all FMD related activities in the country and any zones. Provide maps and tables wherever possible.

c) Provide a description on the involvement and the participation of industry, producers, farmers, including subsistence and small scale producers, community animal health workers and the role of the private veterinary profession in FMD surveillance and control. Include a description of training and awareness programmes on FMD.

d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.

3. FMD control

a) Provide a description of the FMD history in the country and any zones, including date of first detection, origin of infection, date of implementation of the control programme in the country and any zones, and types and subtypes of the FMD virus present.

b) Describe the general epidemiology of FMD in the country and the surrounding countries or zones highlighting the current knowledge and gaps.

b) Describe how FMD is controlled in the country or any zones. Submit a detailed plan on the measures to control and eventually eradicate FMD in the country. Include the timelines of the control programme and the performance indicators to assess the efficacy of the control measures and plan.

c) Provide a description of the legislation, organisation and implementation of the FMD control programme at the different levels. Indicate if detailed operational guidelines exist and give a brief summary. Describe the funding for the control programme and annual budgets for the duration of the control programme.

Annex XVII (contd)

d) Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process of the vaccines used. Describe the vaccination programme in the country and in any zones, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, population immunity, etc.). Provide details on the studies carried out to determine the population immunity, indicating the study design, including threshold levels for within herd protective immunity and minimal herd level immunity. Provide details, if applicable, on a proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the OIE *Terrestrial Manual* to enable demonstration of absence of virus circulation.

e) Provide a description of the methods of animal identification (at the individual or group level), herd registration and traceability; and how the movements of animal and products are assessed and controlled, including movement of infected animals to slaughter. Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe measures to prevent introduction of the virus from neighbouring countries or zones.

4. FMD surveillance

Provide documentary evidence on whether surveillance for FMD in the country complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Describe the criteria for raising a suspicion of FMD and the procedure to notify (by whom and to whom) and what penalties are involved for failure to report.

b) Describe how clinical surveillance is conducted, including which levels of the livestock production system are included in clinical surveillance (e.g. farms, markets, fairs, slaughterhouses, check points, etc.). Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested in diagnostic laboratories. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators. Explain whether serological and virological surveys are conducted and, if so, how frequently and for what purpose.

c) Provide a summary table indicating, for at least 2 consecutive years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.

d) Provide information on livestock demographics and economics, including the susceptible animal population by species and production systems in the country and the zone. Identify how many herds, flocks, etc., of each susceptible species are in the country and how they are distributed (e.g., herd density, etc.). Provide tables and maps as appropriate.

e) Provide information on wildlife demographics, including which susceptible species are present in the country and any zones. Provide estimates of population sizes and geographic distribution. Identify whether susceptible wildlife are included in surveillance. Identify the measures in place to prevent contact between domestic and susceptible wildlife.

f) Identify the major livestock slaughter, marketing and collection centres. Provide information on the patterns of livestock movement within the country, including how animals are transported and handled during these transactions.

5. FMD laboratory diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the *competent authority* to diagnose FMD. If not, provide the name(s) of and the arrangements with the laboratory (ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. If applicable, indicate the laboratory (ies) where samples originating from any zone are diagnosed. Is there regular submission of samples from the country or zone to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the *Terrestrial Manual*?

b) Provide an overview of the FMD approved laboratories, in particular to address the following points.

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.

ii) Give details on participation in inter-laboratory validation tests (ring tests).

iii) Is live virus handled?

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country. In particular provide details on:

a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and zones that should be taken into account (e.g. size, distance from adjacent border to affected herds or animals, surveillance carried in adjacent countries). Describe coordination, collaboration and information sharing activities with neighbouring countries and zones. Describe the measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation of the agent within the country or zone.

b) Provide information on countries or zones from which the country authorises the import of susceptible animals or their products into the country or zone. Describe the criteria applied to approve such countries or zones, the controls applied on entry of such animals and products, and subsequent internal movement. Describe the import conditions and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period, and if so, the duration and location of quarantine. Advise whether import permits and health certificates are required. Describe any other procedures used. Provide summary statistics on imports of susceptible animals and their products for at least 2 consecutive years, specifying country or zone of origin, the species and the number or volume.

i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the official service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible to supervise this and provide a summary, for the past 2 years, of the quantity disposed of.

Annex XVII (contd)

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow up of the following:

- animals,
- genetic material (semen and embryos),
- animal products,
- veterinary medicinal products (i.e. biologics).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports, if available.

7. Control measures and emergency response

a) Give details of any written guidelines, including emergency response plans, available to the official services for dealing with suspected or confirmed outbreaks of FMD.

b) Advise whether quarantine is imposed on premises with suspicious cases, pending final diagnosis and any other procedures followed in respect of suspicious cases.

c) In the event of a FMD outbreak:

i) Provide a detailed description of procedures that are followed in case of an outbreak including forward and backward tracing.

ii) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

iii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;

iv) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial slaughter/vaccination, etc.) that would be taken;

v) describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking;

vi) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for disease control or eradication purposes and their prescribed timetable.

8. Recovery of status

Countries applying for recovery of the official endorsement of the national FMD control programme should provide updated information in compliance with the provisions of Article 8.5.7.bis of the *Terrestrial Code.*

Annex XVIII

CHAPTER 8.10.

RABIES

EU comments

The EU thanks and supports the OIE for this very important work that lead to the proposed new version of the chapter.

However, the chapter is still not satisfactory and need some more change. Comments are inserted in the text in order to improve it.

In any case, it might be better to wait until the *Manual of Standards* has been updated before adopting the new chapter in the Code. Thus, this chapter should not be proposed for adoption before 2012.

Article 8.10.1.

General provisions

Rabies is a disease caused by any member of the *Lyssavirus* genus. All mammals including human are susceptible to infection. Carnivora and Chiroptera are the reservoirs for rabies.

EU comment

The first sentence above is completely in contradiction with the case definition below, which takes into account the new taxonomy of the Lyssavirus genus.

The sentence should read: "For the purposes of the *Terrestrial Code*, rabies is a disease caused by one member of the *Lyssavirus* genus: the *Rabies virus*."

Accordingly, the word "vampire" should be inserted between the words "and" and "Chiroptera" and the word "rabies" should be replaced by "rabies virus".

The new taxonomy of the Lyssavirus genus should also be reflected in the *Manual*. The current draft should not be proposed for adoption before the Manual Chapter has been updated.

For the purposes of the *Terrestrial Code*:

1. a *case* is any animal infected with the *Rabies virus* species;

EU comment

The word "animal" should be in italics.

The EU asks the OIE TAHSC to precise if the human species is included in the point 1 above, and would favour it, since the definition of *animal* in the Glossary includes all types of mammals. If this is not the case, 8.10.2 point 4 needs to be modified to include human cases.

2. the *incubation period* for rabies is variable, but will be considered less than 6 months, and the *infective period* for dogs, cats and ferrets is considered to start 10 days before the onset of the first apparent clinical signs.

EU comments

The words "will be" should be replaced by "are", to be consistent with the formulation used in the Code.

Moreover, the words "dogs, cats and ferrets" should here be replaced by "carnivores", since this point is dealing with the disease in general.

The EU asks the OIE TAHSC to give the scientific justification supporting the change from 15 to 10 days of the infective period.

The aim of this chapter is to mitigate the risk related to rabies for international trade and non-commercial movements of rabies susceptible species.

The most important species for international trade purposes are domestic carnivores (primarily dogs (*Canis familiaris*), cats (*Felis catus)* and ferrets (*Mustela putorius furo*)) and also include domestic livestock (equids, ruminants and suids).

EU comment

For better clarity, the word "host" should be inserted before "species" and the words "involved in international trade" should replace "for international trade purposes".

Rabies can be suspected based on clinical signs or history of exposure to a rabid animal. Confirmation requires antigen detection or virus isolation. Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

EU comment

This paragraph should be placed in point 1 above.

Members are encouraged to implement and maintain a programme for the management of stray dog populations consistent with Chapter 7.7.

Article 8.10.2.

Rabies free country

A country may be considered free from rabies when:

1. the disease is notifiable and any change in the epidemiological situation or relevant events should be reported in accordance with Chapter 1.1.;

2. an effective system of *disease surveillance* has been in operation for the last 2 years, with a minimum requirement being an on-going early detection programme to ensure investigation and reporting of rabies suspect animals;

3. regulatory measures for the prevention of rabies are implemented consistent with the recommendations in this Chapter, including effective procedures for the importation of domestic dogs, cats and ferrets;

EU comments on points 2 and 3 above, applicable to article 8.10.3 below

This chapter does not give any recommendations on surveillance or on regulatory measures for the prevention of rabies to be implemented, except a reference to Chapter 7.7.

There should be guidance on how to implement a vaccination campaign, on dogs or other domestic carnivores or wild carnivores, to be used by countries seeking freedom as a result of an eradication programme.

A reference at least to the chapter 1.4 on surveillance should be inserted in the point 2 above. Moreover, new articles should be drafted on specific rabies surveillance and vaccination, as in other chapters such as FMD.

This should be done in conjunction with the current work on the Rabies chapter of the Manual and with the recommendations of the WHO, for coherence and to avoid repetition.

4. no *case* of indigenously acquired *rabies virus* infection has been confirmed during the past 2 years;

EU comment

If cases in human are not included in the definition of a case in article 8.10.1, the point 4 above should read: "no <u>case</u> <u>in animal or human</u> etc".

5. no imported *case* in reservoir species has been confirmed outside a *quarantine station* for the past 6 months;

6. an imported human *case* of rabies will not affect the rabies free status.

Members should implement and maintain a programme for the management of stray dog populations consistent with Chapter 7.7.

Article 8.10.3.

Country free from dog to dog transmission of rabies

EU comment

The EU asks the OIE to clarify if it is scientifically possible to distinguish an infection transmitted by a dog from that by another animal. No reference to that possibility exists in the *Manual*. If such distinction is not possible, then the whole article is useless and should be deleted as well as the article 8.10.6.

A country may be considered free from dog to dog transmission of rabies when:

1. the disease is notifiable and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;

2. an effective system of *disease surveillance* has been in operation for the last 2 years, with a minimum requirement being an on-going early detection programme to ensure investigation and reporting of suspect animals;

3. regulatory measures for the prevention and control of rabies are implemented consistent with the recommendations in this Chapter, including vaccination, identification and effective procedures for the importation of domestic dogs, cats and ferrets;

4. thorough epidemiological investigations have demonstrated no case of dog to dog transmission of rabies during the past 2 years.

Members should implement and maintain a programme for the management of stray dog populations consistent with Chapter 7.7.

EU comment

There should be inserted an article defining what is an infected country. Considering the ubiquity of the disease, it should be defined as follows:

"<u>For the purpose of this chapter, a Rabies infected country is one that does not fulfil the requirements to qualify as either rabies free country or country free from dog to dog transmission of rabies</u>".

Article 8.10.4.

Recommendations for importation from rabies free countries

for domestic mammals, and captive wild mammals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of rabies the day prior to or on the day of shipment;
2. and either
   a) were kept since birth or at least 6 months prior to shipment in the free country; or
   b) were imported in conformity with the regulations stipulated in Articles 8.10.7., 8.10.8., 8.10.9. or 8.10.10.

Article 8.10.5.

Recommendations for importation from rabies free countries

for wild mammals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of rabies the day prior to or on the day of shipment;
2. and either
   a) have been captured and remained in a rabies free country, at a sufficient distance, based on the biology of species, including home range, from any infected country. The distance should be defined according to the species exported and the reservoir species in the neighbouring infected countries; or
   b) were kept for the 6 months prior to shipment in a rabies free country.

Article 8.10.6

Recommendations for importation of dogs from countries free from dog to dog transmission of rabies

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the dogs:

EU comment

In order to better guide the OIE Members, a reference could be added in the sentence above, to the chapter 5.11 as follows:

"*Veterinary Authorities* should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11, attesting that the dogs"

1. were kept for at least the 6 months prior to shipment in a country free from dog to dog transmission of rabies;
2. were permanently identified (e.g, by a microchip or tattoo) and the identification number should be stated in the *certificate*;
3. received, prior to shipment, a valid anti-rabies vaccination, in accordance with the *Terrestrial Manual*, or revaccination if applicable, in accordance with the recommendations of the manufacturer;

EU comment

The EU wishes that the OIE explains the signification of a "valid" vaccination. There is no such definition in the Manual and this should be explained in this chapter. In the EU, a vaccination is considered valid:

- 21 days after the primo-injection and

- until revaccination is due in accordance with the recommendations made by the manufacturer in the technical specification to the marketing authorisation and

- if further revaccination is performed with no gaps (in case of gap between two consecutive vaccinations then the animal is considered to be a primo-vaccinate).

4. showed no clinical sign of rabies the day prior to or on the day of shipment;

Article 8.10.7.

Recommendations for importation of dogs, cats and ferrets from countries considered infected with rabies

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

EU comment

In order to better guide the OIE Members, this provision should be in line with that of the note accompanying the model international veterinary certificate, in particular when it refers to the meaning of a positive result.

Thus, a reference to the chapter 5.11 could be added in the sentence above, as follows:

"*Veterinary Authorities* should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11, attesting that the animals"

1. showed no clinical sign of rabies the day prior to or on the day of shipment;

AND EITHER

2. were permanently identified (e.g., by a microchip or tattoo) and their identification number should be stated in the *certificate*; and

3. received, prior to shipment, a valid anti-rabies vaccination in accordance with the *Terrestrial Manual*, or revaccination if applicable, in accordance with the recommendations of the manufacturer; and

EU comment

The Manual does not provide guidance on the vaccination protocol. The words "in accordance with", should thus be replaced by: "with a vaccine complying with the standards of the".

4. were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result;

OR

5. have not been vaccinated against rabies or do not meet all the conditions set out in points 2, 3 and 4 above; in such cases, the animals should be quarantined for 6 months prior to export.

EU comment

The word "quarantined" should be replaced by "isolated from any other mammals under veterinary supervision" or "maintained in a *quarantine station*".

Article 8.10.8.

Recommendations for importation of domestic ruminants and suids from countries considered infected with rabies

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of rabies the day prior to or on the day of shipment.

EU comment

The EU does not recognise difference of risk between ruminants, suids and equids in the epidemiology of rabies. All species are equally victims and extremely rarely involved in the transmission of the virus. The proposed article 8.10.8 is not enough stringent while the article 8.10.9 is too stringent. Indeed, the risk represented by equids is not high enough to justify so stringent measures as in article 8.10.9. Thus the two articles should be merged to reflect doable and efficient risk management measures, and should read:

"Recommendations for importation of domestic ruminants, suids and equids from countries considered infected with rabies

***Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals:**

1. showed no clinical sign of rabies the day prior to or on the day of shipment;

2. and either;

a) were kept since birth or for the 6 months prior to shipment in *establishments* where no *case* of rabies was reported during that period;

or

b) were vaccinated with a vaccine complying with the standards of the *Terrestrial Manual*."

Article 8.10.9.

Recommendations for importation of domestic equids from countries considered infected with rabies

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of rabies the day prior to or on the day of shipment;

2. and either;

   a) were kept for the 6 months prior to shipment in an *establishment* where no contact with reservoir species was maintained and where no *case* of rabies was reported for at least 12 months prior to shipment; or

   b) were vaccinated as prescribed in the *Terrestrial Manual.*

EU comment

See comment above: this article could block all trade between countries not free from rabies and should be merged with article 8.10.8.

The Manual does not provide guidance on the vaccination protocol. The words "as prescribed in", should thus be replaced by: "with a vaccine complying with the standards of the".

Article 8.10.10.

Recommendations for importation from countries considered infected with rabies

for rodents and lagomorphs born and reared in a biosecure facility

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of rabies on the day of shipment;

2. were kept since birth in a biosecure facility an *establishment* where no *case* of rabies was reported for at least 12 months prior to shipment.

Article 8.10.11.

Recommendations for importation from countries considered infected with rabies

for captive wild animals (other than non-human primates)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of rabies the day prior to or on the day of shipment;

2. were kept since birth, or for the 6 months prior to shipment, in an *establishment* where no contact with reservoir species and where no *case* of rabies was reported for at least 12 months prior to shipment.

EU comment

The sentence above is unclear. It should read: "in an *establishment* where they had no contact with reservoir species".

Article 8.10.12.

Recommendations for importation from countries considered infected with rabies

for *wild* and *feral animals* (other than non-human primates and Chiroptera)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of rabies the day prior to or on the day of shipment;

2. were kept for the 6 months prior to shipment in an *establishment* where separation from wild animals and feral animals was maintained and where no *case* of rabies was reported for at least 12 months prior to shipment.

EU comment

Does the fact that there are no recommendations for importations of wild Chiroptera from countries considered infected with rabies, means that these importations should not take place? In that case, it should be explicitly mentioned here or in another article. But as the chapter deals with rabies virus, it seems that the risk of importing a wild carnivore is higher than that of a wild chiroptera. The EU wishes the OIE explains this point.

Article 8.10.13.

Recommendations for importation from countries considered infected with rabies

for captive non-human primates

1. showed no clinical sign of rabies the day prior to or on the day of shipment;

2. quarantine measures were applied in accordance with Chapter 5.9. and Chapter 6.11.

Annex XVIII (contd)

CHAPTER 5. 11.

RABIES

EU comment
The title of the Chapter should not be "Rabies"; it is confusing with chapter 8.10. Furthermore, this model certificate can apply as a general model, and it is repeated in parts IV to VI that they apply on rabies.
Thus the word "rabies" above should be deleted.
Moreover, some comments are inserted in the notes for clarity and coherence.

MODEL INTERNATIONAL VETERINARY CERTIFICATE FOR DOMESTIC DOGS (*Canis familiaris*), ~~AND~~ CATS (*Felis catus*) AND FERRETS (*Mustela putorius furo*) ~~ORIGINATING FROM RABIES INFECTED COUNTRIES~~

I. OWNER

Name and address: .....
.....
.....
.....

II. DESCRIPTION

Species of animal: .....
Age or date of birth: .....
Sex: .....
Breed: .....
Colour: .....
Coat type and marking/Distinguishing marks: .....
.....
.....
.....
Identification number (tattoo or other permanent method of identification) (see note 1)

EU comment
The location of identification number should be added in the point above.

III. ADDITIONAL INFORMATION

Country of origin: .....
.....
Countries visited .....
over the past 2 years .....
as declared by the owner .....
(give dates) .....
.....
.....

IV. VACCINATION (Rabies)

I the undersigned declare herewith that I have vaccinated the animal described in Part II against rabies as shown below. The animal was found to be healthy on the day of vaccination.

Date of vaccination (dd/mm/yy)	Name of inactivated virus vaccine (see note 2)	1. Manufacturing laboratory 2. Batch number 3. Expiry date	Name (in capital letters) and signature of the veterinarian (see note 6)
		1..... 2…….. 3.....	

PERIOD OF VALIDITY OF VACCINATION FOR INTERNATIONAL MOVEMENT (see note 3)		Name (in capital letters) and signature of the Official Veterinarian
from (dd/mm/yy)	to (dd/mm/yy)	

Annex XVIII (contd)

V. SEROLOGICAL TESTING (Rabies)

I the undersigned declare herewith that I have taken a blood sample from the animal described in Part II and have received the following result from the official diagnostic laboratory which has carried out the ~~neutralising~~ antibody titration test (see note 4).

Date of sampling (dd/mm/yy)	Name and address of the official diagnostic laboratory	Result of the antibody titration test (in International Units [IU]/ml)	Name (in capital letters) and signature of the veterinarian (see note 6)

PERIOD OF VALIDITY OF SEROLOGICAL TESTING FOR INTERNATIONAL MOVEMENT (see note 3)		Name (in capital letters) and signature of the Official Veterinarian
from (dd/mm/yy)	to (dd/mm/yy)	

VI. CLINICAL EXAMINATION (Rabies)

I the undersigned declare herewith that I have examined on the date indicated below the animal described in Part II and have found it to be clinically healthy (see note 5).

Date (dd/mm/yy)	Name (in capital letters) and signature of the veterinarian (see note 6)	Name (in capital letters) and signature of the Official Veterinarian

NOTE

1. The identification number stated in the certificate should be identical to that which can be found on the animal. When electronic identification is used, the type of microchip and the name of the manufacturer should be specified.

2. Only vaccines that comply with the recommendations of the *Terrestrial Manual* ~~inactivated virus vaccines are authorised for international movements of dogs and cats~~.

3. ~~In the case of a primary~~ Vaccination or re-vaccination should be carried out in accordance with the recommendations of the manufacturer ~~the animal should have been vaccinated not less than 6 months and not more than 1 year prior to its introduction into the importing country; the vaccination should have been carried out when the animal was at least 3 months old~~.

   ~~In the case of a booster vaccination, the animal should have been vaccinated not more than 1 year prior to its introduction into the importing country.~~

4. The animal should have been subjected not less than 3 months and not more than ~~24~~12 months prior to its introduction into the importing country, to a ~~neutralising~~ antibody titration test. It should be carried out by an official diagnostic laboratory approved by the Competent Authority of the exporting country. The animal's serum should contain at least 0.5 International Units (IU)/ml.

EU comment

Part V of the certificate is not applicable to all animals (i.e. not to dogs originating from a country free from dog to dog transmission of rabies). Thus point 4 above should begin with: "When serological testing is required,"

Moreover, the positive threshold might be different according to the Manual. Thus the point 4 should be written in the same way as the article in the Rabies chapter: the last sentence should be deleted, and the first sentence should read:

"When serological testing is required, the animal should have been subjected not less than 3 months and not more than 12 months prior to its introduction into the importing country, to an antibody titration test~~. It should be~~, carried out by an official diagnostic laboratory approved by the Competent Authority of the exporting country, with positive result in accordance with the *Terrestrial Manual*."

5. The clinical examination referred to in Part VI of the certificate must be carried out within 48 hours of shipment.

EU comment

The wording of point 5 above "within 48 hours of shipment" should be clarified so that it is not in contradiction with the rabies chapter, i.e. "the day prior to or on the day of shipment".

The Competent Authority of the importing country may require the placing of the animals which do not comply with any of the above-mentioned conditions in a quarantine station

located on its territory; the conditions of stay in quarantine are laid down by the legislation of the importing country.

6. If the veterinarian whose name and signature appear on the certificate is not an official veterinarian, his signature must be authenticated in the relevant column by the signature and stamp of an official veterinarian. The expression 'Official Veterinarian' means a civil service veterinarian or a specially appointed veterinarian, as authorised by the Veterinary Authority of the country.

7. If so required, the certificate should be written in the language of the importing country. In such circumstances, it should also be written in a language understood by the certifying veterinarian.

Annex XIX

CHAPTER 8.15.

VESICULAR STOMATITIS

EU comment

The EU cannot support the proposed change. In article 8.15.6, points 2 and 3 (proposed 2a) and b)) are not at all equivalent in terms of risk reduction, and cannot be put as alternatives.

Article 8.15.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for vesicular stomatitis (VS) shall be 21 days.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 8.15.2.

VS free country

A country may be considered free from VS when:

1. VS is notifiable in the country;
2. no clinical, epidemiological or other evidence of VS has been found during the past 2 years.

Article 8.15.3.

Trade in commodities

Veterinary Authorities of countries shall consider whether there is a risk with regard to VS in accepting importation or transit through their territory, from other countries, of ruminants, swine, Equidae, and their semen and embryos.

Article 8.15.4.

Recommendations for importation from VS free countries

for domestic cattle, sheep, goats, pigs and horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of VS on the day of shipment;
2. were kept in a VS free country since birth or for at least the past 21 days.

Article 8.15.5.

Recommendations for importation from VS free countries

for wild bovine, ovine, caprine, porcine and equine animals and deer

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of VS on the day of shipment;

2. come from a VS free country;

Annex XIX (contd)

if the country of origin has a common border with a country considered infected with VS:

3. were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;

4. were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 8.15.6.

Recommendations for importation from countries considered infected with VS

for domestic cattle, sheep, goats, pigs and horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of VS on the day of shipment;

2. either

   a) were kept, since birth or for the past 21 days, in an *establishment* where no *case* of VS was officially reported during that period; or

   ~~3.~~b) were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;

EU comment

The EU cannot support the proposed change. Points 2 and 3 (proposed 2)a) and b) above are not at all equivalent in terms of risk reduction, and cannot be put as alternatives. The former version of the Chapter was wrong and it might have been a mistake: it should be 2 and 3. If not then the conditions to import from an infected country are milder than the one from a free country bordering an infected one… (See article 8.15.5 point 3.)

~~4~~3. were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 8.15.7.

Recommendations for importation from countries considered infected with VS

for wild bovine, ovine, caprine, porcine and equine animals and deer

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of VS on the day of shipment;

2. were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;

3. were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 8.15.8.

Recommendations for importation from VS free countries or zones

for *in vivo* derived embryos of ruminants, swine and horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females were kept in an *establishment* located in a VS free country or zone at the time of collection;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.15.9.

Recommendations for importation from countries or zones considered infected with VS

for *in vivo* derived embryos of ruminants, swine and horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

   a) were kept for the 21 days prior to, and during, collection in an *establishment* where no *c a se* of VS was reported during that period;

   b) were subjected to a diagnostic test for VS, with negative results, within the 21 days prior to embryo collection;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

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— text deleted

Annex XX

CHAPTER 4.14.

HYGIENE AND DISEASE SECURITY PROCEDURES IN APIARIES

EU comment

The EU can support the proposed changes, but has some comments.

Article 4.14.1.

In each country, official health control of bee *diseases* should include:

a) an organisation for permanent health *surveillance*;

b) approval of breeding apiaries for export trade;

c) measures for cleaning, *disinfection* and *disinfestation* of apicultural equipment;

d) rules precisely stating the requirements for issuing an *international veterinary certificate*.

Article 4.14.2.

Organisation for permanent official sanitary surveillance of apiaries

Permanent official sanitary *surveillance* of apiaries should be under the authority of the *Veterinary Authority* and should be performed either by representatives of this Authority or by representatives of an approved organisation, with the possible assistance of bee-keepers specially trained to qualify as 'health inspectors and advisers'.

The official *surveillance* service thus established should be entrusted with the following tasks:

1. visit apiaries:

    a) annual visits during the most appropriate periods for the detection of *diseases*;

    b) unexpected visits to apiaries where breeding or transport operations are carried out for trade or transfer to other regions, or any other purpose whereby *diseases* could be spread, as well as to apiaries located in the vicinity;

    c) special visits for sanitary *surveillance* to sectors where breeding apiaries have been approved for export purposes;

2. collect the samples required for the diagnosis of contagious *diseases* and despatch them to an official laboratory; the results of laboratory examinations ~~must~~ should be communicated within the shortest delay to the *Veterinary Authority*;

3. apply hygiene measures, comprising, in particular, treatment of colonies of bees, as well as *disinfection* of the equipment and possibly the destruction of affected or suspect colonies and of the contaminated equipment so as to ensure rapid eradication of any *outbreak* of a contagious *disease*.

Article 4.14.3.

Conditions for approval of breeding apiaries for export trade

The apiaries ~~must~~ should:

1. be situated in the centre of an area ~~defined as follows and~~ in which~~:~~

   ~~a)~~ ~~no *case* of varroosis has been reported for at least the past 2 years within a radius of 50 kilometres;~~

   ~~b)~~ no *case* of ~~any other~~ contagious *disease* of bees included in this *Terrestrial Code* has been reported for at least the past 8 months within a radius of 5 kilometres;

EU comment

In the point 1 above, the word "this" should be replaced by "the".

The radius of 5 kilometres has no real meaning relating to no specific diseases. Even if one considers the average flight distance of a bee (3 km), it should be 6 km; and if on considers infestation with small hive beetle that can fly itself, it is indeed much more.

Thus, the end of point 1 above should read: "within a radius ~~of 5 kilometres~~ defined by the *Veterinary Services* depending of the diseases present in the country, or complying with recommendations of chapters 9.1 to 9.6;"

2. have received, for at least the past 2 years, visits by a health inspector and adviser, carried out at least ~~3~~ 2 times a year (~~in spring,~~ during the breeding period and in autumn), for the systematic examination of at least 10% of the hives containing bees and of all the apicultural equipment, and for the collection of samples to be sent to an official laboratory.

Bee-keepers ~~must~~ should:

3. immediately notify the *Veterinary Authority* of any suspicion of a contagious *disease* of bees in the breeding apiary and in other apiaries in the vicinity;

4. not introduce into the apiary any bee (including larval stages) or apicultural material or product originating from another apiary unless health control has been previously performed by the *Veterinary Authority*;

EU comment

In order to be more precise, the word "larval" should be replaced by "pre-imago".

5. apply special breeding and despatch techniques to ensure protection against any outside contamination, especially for the breeding and sending of queen-bees and accompanying bees and to enable retesting in the *importing country*;

6. collect at least every ~~10~~ 30 days, during the breeding and despatch period, samples from breeding material, brood-combs, queen-bees and bees (including possibly separately raised accompanying bees), to be sent to an official laboratory.

EU comment

The EU would like to know how queen bees can be sampled every 30 days, or if the word "and" could be replaced by "or".

Article 4.14.4.

Conditions for sanitation and disinfection of apicultural equipment

Veterinary Authorities of *exporting countries* are requested to regulate the use of products and means for sanitation and *disinfection* of apicultural equipment in their own country, taking into account the following recommendations.

1. Any apicultural equipment kept in an *establishment* which has been recognised as being affected with a contagious *disease* of bees shall be subjected to sanitary measures ensuring the elimination of pathogens.

2. In all cases, these measures comprise the initial cleaning and scraping of the equipment, followed by sanitation or *disinfection* depending on the *disease* concerned.

3. The kind of equipment (hives, small hives, combs, extractor, small equipment, appliances for handling or storage) shall also be taken into account in the choice of procedures to be applied.

4. Infected or contaminated equipment which cannot be subjected to the above-mentioned measures ~~must~~ should be destroyed, preferably by burning. Any equipment in bad condition, especially hives, as well as larvae in combs affected with varroosis, American foulbrood or European foulbrood, ~~must~~ should be destroyed by burning.

EU comment

The wording "bad condition" is unclear. It should be replaced by other terms, such as "not in good functioning condition".

5. The products and means used for sanitation and *disinfection* shall be recognised as being effective by the *Veterinary Authority*. They shall be used in such a manner as to exclude any risk of contaminating the equipment which could eventually affect the health of bees or adulterate the products of the hive.

6. When these procedures are not performed, the products shall be kept away from the bees and any contact with apicultural equipment and products ~~must~~ should be prevented.

7. Waste water from the cleaning, sanitation and *disinfection* of apicultural equipment shall be kept away from the bees at all times and disposed of in a sewer or in an unused well.

Article 4.14.5.

Preparation of the international veterinary certificate for export

This Certificate covers hives containing bees, swarms, consignments of bees (worker bees or drones), queen bees (with accompanying bees), brood-combs, royal cells, etc.

This document shall be prepared in accordance with the model contained in Chapter 5.10.

– text deleted

Annex XX (contd)

CHAPTER 9.1.

ACARAPISOSIS OF HONEY BEES

EU comment

The EU thanks the OIE TAHSC and can support the proposed changes.

However, comments are inserted in the text for better consistence with the risk represented by "free apiaries" in non free country or zones.

Article 9.1.1.

General provisions

For the purposes of this Chapter, acarapisosis, acarine disease or tracheal mite infestation is a *disease* of the adult honey bee *Apis mellifera L.*, and possibly of other *Apis* species (such as *Apis cerana*). It is caused by the Tarsonemid mite *Acarapis woodi* (Rennie). The mite is an internal obligate parasite of the respiratory system, living and reproducing mainly in the large prothoracic trachea of the bee. Early signs of *infection* normally go unnoticed, and only when *infection* is heavy does it become apparent; this is generally in the early spring. The *infection* spreads by direct contact from adult bee to adult bee, with newly emerged bees under 10 days old being the most susceptible. The mortality rate may range from moderate to high.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.1.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the acarapisosis status of the honey bee population of the *exporting country* or *zone.*

Article 9.1.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any acarapisosis related conditions, regardless of the acarapisosis status of the honey bee population of the *exporting country* or *zone*:

1. honey bee semen and honey bee venom;

2. used equipment associated with beekeeping;

3. extracted honey, pollen, propolis, royal jelly for human consumption, and processed beeswax~~, honey bee-collected pollen, propolis and royal jelly~~.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the acarapisosis status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.1.3.

Determination of the acarapisosis status of a country or zone~~/compartment~~

The acarapisosis status of a country or *zone~~/compartment~~* ~~(under study)~~ can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for acarapisosis occurrence and their

historic perspective;

2. acarapisosis should be notifiable in the whole country or *zone/ ~~compartment~~* ~~(under study)~~ and all clinical signs suggestive of acarapisosis should be subjected to field and laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of acarapisosis;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the whole country.

Article 9.1.4.

Country or zone~~/ compartment (under study)~~ free from acarapisosis

1. Historically free status

A country or *zone ~~/ compartment~~* ~~(under study)~~ may be considered free from acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.3. but without formally applying a specific *surveillance* programme if the country or *zone/ ~~compartment~~* ~~(under study)~~ complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or *zone/ ~~compartment~~* ~~(under study)~~ which does not meet the conditions of point 1 above may be considered free from acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.3. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/ ~~compartment~~* ~~(under study)~~;

b) acarapisosis is notifiable in the whole country or *zone/ ~~compartment~~* ~~(under study)~~, and any clinical cases suggestive of acarapisosis are subjected to field and laboratory investigations;

c) for the 3 years following the last reported *case* of acarapisosis, annual surveys supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/ ~~compartment~~* ~~(under study)~~ to provide a confidence level of at least 95% of detecting acarapisosis if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards *apiaries*, areas and seasons with a higher likelihood of *disease*;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone/ ~~compartment~~* ~~(under study)~~ to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

e) (under study) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or *zone/ ~~compartment~~* ~~(under study)~~;

f) the importation of the *commodities* listed in this Chapter into the country or *zone/ ~~compartment~~* ~~(under study)~~ is carried out in conformity with the recommendations of this Chapter.

Article 9.1.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/ ~~compartment~~* ~~(under study)~~ free from acarapisosis or the apiary

meets the conditions prescribed in Article 4.14.3.

EU comment

The risk represented by "free apiaries" according to article 4.14.3 in non free country or zones is higher than free countries or zones.

Thus, the following words should be added to the paragraph above:

"and a statistically valid number of animals were examined microscopically or by any other method complying with the *Terrestrial Manual* and found free of all life stages of *A. woodi*."

Article 9.1.6.

Recommendations for the importation of eggs, larvae and pupae of honey bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. were sourced from an officially free country or *zone/ ~~compartment~~* ~~(under study)~~; or

2. were examined by an official laboratory and declared free of all life stages of *A. woodi*; or

3. have originated from queens in a *quarantine station* and were examined microscopically and found free of all life stages of *A. woodi*.

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– text deleted

Annex XX (contd)

CHAPTER 9.2.

AMERICAN FOULBROOD OF HONEY BEES

EU comment

The EU thanks the OIE TAHSC and can support the proposed changes.

However, comments are inserted in the text for better consistence with the risk represented by "free apiaries" in non free country or zones.

Article 9.2.1.

General provisions

For the purposes of this Chapter, American foulbrood is a *disease* of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. *Paenibacillus larvae*, the causative organism, is a bacterium that can produce over one billion spores in each infected larva. The spores are very long-living and extremely resistant to heat and chemical agents, and only the spores are capable of inducing the *disease*.

Combs of infected *apiaries* may show distinctive clinical signs which can allow the *disease* to be diagnosed in the field. However, subclinical *infections* are common and require laboratory diagnosis.

For the purposes of the *Terrestrial Code*, the *incubation period* for American foulbrood shall be 15 days (not including the wintering period which may vary according to country).

Standards for diagnostic tests are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the American foulbrood status of the honey bee population of the *exporting country* or *zone.*

Article 9.2.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any American foulbrood related conditions, regardless of the American foulbrood status of the honey bee population of the *exporting country* or *zone*:

1. honey bee semen;

2. honey bee venom.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the American foulbrood status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.2.3.

Determination of the American foulbrood status of a country or zone~~/ compartment~~

The American foulbrood status of a country or *zone~~/ compartment~~* ~~(under study)~~ can only be determined after

considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for American foulbrood occurrence and their historic perspective;
2. American foulbrood should be notifiable in the whole country or *zone/~~compartment~~* ~~(under study)~~ and all clinical signs suggestive of American foulbrood should be subjected to field and/or laboratory investigations;
3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of American foulbrood;
4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.2.4.

Country or zone~~/ compartment (under study)~~ free from American foulbrood

1. Historically free status

   A country or *zone/~~compartment~~* ~~(under study)~~ may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.2.3. but without formally applying a specific *surveillance* programme if the country or *zone/~~compartment~~* ~~(under study)~~ complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

   A country or *zone/~~compartment~~* ~~(under study)~~ which does not meet the conditions of point 1 above may be considered free from American foulbrood after conducting a *risk assessment* as referred to in Article 9.2.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/~~compartment~~* ~~(under study)~~;

   b) American foulbrood is notifiable in the whole country or *zone ~~/compartment~~* ~~(under study)~~, and any clinical cases suggestive of American foulbrood are subjected to field and/or laboratory investigations;

   c) for the 5 years following the last reported isolation of the American foulbrood agent, annual surveys supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/~~compartment~~* ~~(under study)~~ to provide a confidence level of at least 95% of detecting American foulbrood if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the American foulbrood agent;

   d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of hives in the country or *zone/~~compartment~~* ~~(under study)~~ to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;

   e) (under study) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or *zone/~~compartment~~* ~~(under study)~~;

   f) all equipment associated with previously infected *apiaries* has been sterilised or destroyed;

   g) the importation of the *commodities* listed in this Chapter into the country or *zone/~~compartment~~* ~~(under study)~~ is carried out in conformity with the recommendations of this Chapter.

Article 9.2.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/~~compartment~~* ~~(under study)~~ ~~officially~~ free from American

foulbrood or the apiary meets the conditions prescribed in Article 4.14.3.

EU comment

The risk represented by "free apiaries" according to article 4.14.3 in non free country or zones is higher than free countries or zones.

Thus, the following words should be added to the paragraph above:

"and a statistically valid number of animals were examined for the presence of P. larvae by bacterial culture or PCR in accordance with the Terrestrial Manual and found free."

Article 9.2.6.

Recommendations for the importation of eggs, larvae and pupae of honey bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. were sourced from a free country or *zone/ compartment* (under study); or

2. have been isolated from queens in a *quarantine station*, and all workers which accompanied the queen or a representative sample of eggs or larvae were examined for the presence of *P. larvae* by bacterial culture or PCR in accordance with the *Terrestrial Manual*.

EU comment

The words "eggs or" should be deleted since the agent is not found in eggs.

Article 9.2.7.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 1% sodium hypochlorite for at least 30 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of both bacillary and spore forms of *P. larvae*, in conformity with one of the procedures referred to in Chapter X.X. recommended by the OIE (under study).

Article 9.2.8.

Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly

Veterinary Authorities of *importing countries* officially free from American foulbrood should require the presentation of an *international veterinary certificate* attesting that the products:

1. were collected in a country or *zone/ compartment* (under study) free from American foulbrood; or

2. have been processed to ensure the destruction of both bacillary and spore forms of *P. larvae*, in conformity with one of the procedures referred to in Chapter X.X. recommended by the OIE (under study).

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CHAPTER 9.3.

EUROPEAN FOULBROOD OF HONEY BEES

EU comment

The EU thanks the OIE TAHSC and can support the proposed changes.

However, comments are inserted in the text for better consistence with the risk represented by "free apiaries" in non free country or zones.

Article 9.3.1.

General provisions

For the purposes of this Chapter, European foulbrood is a *disease* of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. The causative agent is the non-sporulating bacterium *Melissococcus plutonius*. Subclinical *infections* are common and require laboratory diagnosis. *Infection* remains enzootic because of mechanical contamination of the honeycombs. Recurrences of *disease* can therefore be expected in subsequent years.

For the purposes of the *Terrestrial Code*, the *incubation period* for European foulbrood shall be 15 days (not including the wintering period which may vary according to country).

Standards for diagnostic tests are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the European foulbrood status of the honey bee population of the *exporting country* or *zone*.

Article 9.3.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any European foulbrood related conditions, regardless of the European foulbrood status of the honey bee population of the *exporting country* or *zone*:

1. honey bee semen;

2. honey bee venom.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the European foulbrood status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.3.3.

Determination of the European foulbrood status of a country or zone~~/ compartment~~

The European foulbrood status of a country or *zone~~/ compartment~~* ~~(under study)~~ can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for European foulbrood occurrence and their historic perspective;

2. European foulbrood should be notifiable in the whole country or *zone/ ~~compartment~~* ~~(under study)~~ and all clinical signs suggestive of European foulbrood should be subjected to field and laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of European foulbrood;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all *apiaries* in the whole country.

Article 9.3.4.

Country or zone~~/ compartment (under study)~~ free from European foulbrood

1. Historically free status

   A country or *zone ~~/ compartment~~* ~~(under study)~~ may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.3.3. but without formally applying a specific *surveillance* programme if the country or *zone/ ~~compartment~~* ~~(under study)~~ complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

   A country or *zone/ ~~compartment~~* ~~(under study)~~ which does not meet the conditions of point 1 above may be considered free from European foulbrood after conducting a *risk assessment* as referred to in Article 9.3.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/ ~~compartment~~* ~~(under study)~~;

   b) European foulbrood is notifiable in the whole country or *zone/ ~~compartment~~* ~~(under study)~~, and any clinical cases suggestive of European foulbrood are subjected to field and laboratory investigations;

   c) for the 3 years following the last reported isolation of the European foulbrood agent, an annual survey supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/ ~~compartment~~* ~~(under study)~~ to provide a confidence level of at least 95% of detecting European foulbrood if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the European foulbrood agent;

   d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of hives in the country or *zone/ ~~compartment~~* ~~(under study)~~ to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;

   e) (under study) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or *zone/ ~~compartment~~* ~~(under study)~~;

   f) the importation of the *commodities* listed in this Chapter into the country or *zone/ ~~compartment~~* ~~(under study)~~ is carried out in conformity with the recommendations of this Chapter.

Article 9.3.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/ ~~compartment~~* ~~(under study)~~ free from European foulbrood or the apiary meets the conditions prescribed in Article 4.14.3.

EU comment

The risk represented by "free apiaries" according to article 4.14.3 in non free country or zones is higher than free countries or zones.

Thus, the following words should be added to the paragraph above:

"and a statistically valid number of animals were examined for the presence of *M. plutonius* by bacterial culture or PCR in accordance with the Terrestrial Manual and found free."

Article 9.3.6.

Recommendations for the importation of eggs, larvae and pupae of honey bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. were sourced from a free country or *zone/ ~~compartment~~* ~~(under study)~~; or

2. have been isolated from queens in a *quarantine station*, and all workers which accompanied the queen or a representative sample of eggs or larvae were examined for the presence of *M. plutonius* by bacterial culture or PCR in accordance with the *Terrestrial Manual*.

EU comment

The words "eggs or" should be deleted since the agent is not found in eggs.

Article 9.3.7.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 0.5% sodium hypochlorite for at least 20 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of *M. plutonius*, in conformity with one of the procedures ~~referred to in Chapter~~ recommended by the OIE. (under study).

Article 9.3.8.

Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. were collected in a country or *zone/ ~~compartment~~* ~~(under study)~~ free from European foulbrood; or

2. have been processed to ensure the destruction of *M. plutonius*, in conformity with one of the procedures ~~referred to in Chapter X.X.~~ recommended by the OIE (under study).

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– text deleted

Annex XX (contd)

CHAPTER 9.4.

SMALL HIVE BEETLE INFESTATION
(*Aethina tumida*)

EU comment

The EU thanks the OIE TAHSC and can support the proposed changes.

Article 9.4.1.

General provisions

For the purposes of this Chapter, small hive beetle (SHB) is an infestation of social bee colonies by the beetle *Aethina tumida*, which is a free-living predator parasite and scavenger affecting populations of the honey bee *Apis mellifera* L. It can also ~~parasitise~~ invade bumble bee *Bombus terrestris* and stingless bee Trigona carbonaria colonies under experimental conditions~~, and although infestation has not been demonstrated in wild populations, *Bombus* spp. must also be considered to be susceptible to infestation~~.

The adult beetle is attracted to bee colonies to reproduce, although it can survive and reproduce independently in other natural environments, using other food sources, including certain types of fruit. Hence once it is established within a localised environment, it is extremely difficult to eradicate.

~~The life cycle of *A. tumida* begins with the adult beetle laying eggs within infested hives. These are usually laid in irregular masses in crevices or brood combs. After 2-6 days, the eggs hatch and the emerging larvae begin to feed voraciously on brood comb, bee eggs, pollen and honey within the hive. The SHB has a high reproductive potential. Each female can produce about 1,000 eggs in its 4 to 6 months of life. At maturation (approximately 10-29 days after hatching), the larvae exit the hive and burrow into soil around the hive entrance. Adult beetles emerge after an average of 3-4 weeks, although pupation can take between 8 and 60 days depending on temperature and moisture levels.~~

The life span of an adult beetle depends on environmental conditions such as temperature and humidity but, in practice, adult beetles can live for at least 6 months and, in favourable reproductive conditions, the female is capable of laying new egg batches every 5-12 weeks. The beetle is able to survive at least 2 weeks without food ~~and 50 days on brood combs~~.

Early signs of infestation and reproduction in the debris may go unnoticed~~, but the growth of the beetle population is rapid, leading to high bee mortality in the hive~~. When the bees cannot prevent beetle mass reproduction on the combs, this leads to abandonment and or collapse of the colony. Because *A. tumida* can be found and can thrive within the natural environment, and can fly up to 6-13 km from its nest site, it is capable of dispersing rapidly and directly invading new ~~colonising~~ hives. Dispersal of beetles includes following or accompanying swarms of bees. Spread of infestation does not require contact between adult bees. ~~However,~~ tThe movement of adult bees, honeycomb and other apiculture products and used equipment associated with bee-keeping may all cause infestations to spread to previously unaffected colonies.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.4.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *A. tumida* status of the honey bee and other social bee population of the *exporting country* or *zone.*

Article 9.4.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any small hive beetle infestation related conditions, regardless of the *A. tumida* status of the honey bee and bumble bee population of the *exporting country* or *zone*:

1. honey bee semen and honey bee venom;

2. packaged extracted honey for human consumption, refined or rendered beeswax, propolis and frozen or dried royal jelly.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the *A. tumida* status of the honey bee and bumble bee population of the *exporting country* or *zone*.~~

Article 9.4.3.

Determination of the *A. tumida* status of a country or zone

The *A. tumida* status of a country or *zone* can only be determined after considering the following criteria:

1. *A. tumida* infestation should be notifiable in the whole country, and all signs suggestive of *A. tumida* infestation should be subjected to field and *laboratory* investigations;

2. on-going awareness and training programmes should be in place to encourage reporting of all cases suggestive of *A. tumida* infestation;

3. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.4.4.

Country or zone free from *A. tumida*

1. Historically free status

   A country or *zone* may be considered free from the pest after conducting a *risk assessment* as referred to in Article 9.4.3. but without formally applying a specific *surveillance* programme if the country or *zone* complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

   A country or *zone* which does not meet the conditions of point 1 above may be considered free from *A. tumida* infestation after conducting a *risk assessment* as referred to in Article 9.4.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone*;

   b) *A. tumida* infestation is notifiable in the whole country or *zone*, and any clinical cases suggestive of *A. tumida* infestation are subjected to field and *laboratory* investigations; a contingency plan is in place describing controls and inspection activities;

   c) for the 5 years following the last reported *case* of *A. tumida* infestation, an annual survey supervised by the *Veterinary Authority*, with negative results, has been carried out on a representative sample of *apiaries* in the country or *zone* to provide a confidence level of at least 95% of detecting *A. tumida* infestation if at least 1% of the *apiaries* were infested at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;

   d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* to indicate that there have been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of infestation;

   e) all equipment associated with previously infested *apiaries* has been destroyed, or cleaned and sterilised to

ensure the destruction of *A. tumida* spp., in conformity with one of the procedures ~~referred to in Chapter X.X.~~ recommended by the OIE (under study);

f) the soil and undergrowth in the immediate vicinity of all infested *apiaries* has been treated with a soil drench or similar suitable treatment that is efficacious in destroying incubating *A. tumida* larvae and pupae;

g) the importation of the *commodities* listed in this Chapter into the country or *zone* is carried out, in conformity with the recommendations of this Chapter.

Article 9.4.5.

Recommendations for the importation of individual consignments containing a single live queen honey bee or queen bumble bee, accompanied by a small number of associated attendants (a maximum of 20 attendants per queen)

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that

1. the bees come from a country or *zone* officially free from *A. tumida* infestation.

OR

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* including an attestation from the *Veterinary Authority* of the exporting third country stating that:~~

~~1~~2. the bees come from hives or colonies which were inspected immediately prior to dispatch and show no signs or suspicion of the presence of *A. tumida* or its eggs, larvae or pupae; and

~~2~~3. the bees come from an area of at least 100 km radius where no *apiary* has been subject to any restrictions associated with the occurrence of *A. tumida* for the previous 6 months; and

~~3~~4. the bees and accompanying packaging presented for export have been thoroughly and individually inspected and do not contain *A. tumida* or its eggs, larvae or pupae; and

~~4~~5. the consignment of bees is covered with fine mesh through which a live beetle cannot enter.

Article 9.4.6.

Recommendations for the importation of live worker bees, drone bees or bee colonies with or without associated brood combs or for live bumble bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the bees come from a country or *zone* officially free from *A. tumida* infestation; and

2. the bees and accompanying packaging presented for export have been inspected and do not contain *A. tumida* or its eggs, larvae or pupae; and

3. the consignment of bees is covered with fine mesh through which a live beetle cannot enter.

Article 9.4.7.

Recommendations for the importation of eggs, larvae and pupae of honey bees or bumble bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. the products were sourced from a country or *zone* free from *A. tumida* infestation;

OR

2. the products have been bred and kept under a controlled environment within a recognised establishment which is supervised and controlled by the *Veterinary Authority*;

3. the establishment was inspected immediately prior to dispatch and all eggs, larvae and pupae show no clinical signs or suspicion of the presence of *A. tumida* or its eggs or larvae or pupae, and

4. the packaging material, containers, accompanying products and food are new and all precautions have been taken to prevent contamination with *A. tumida* or its eggs, larvae or pupae.

Article 9.4.8.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the equipment:

   EITHER

   a) comes from a country or *zone* free from *A. tumida* infestation; and

   b) contains no live honey bees or bee brood;

   OR

   c) contains no live honey bees or bee brood; and

   d) has been thoroughly cleaned, and treated to ensure the destruction of *A. tumida* spp., in conformity with one of the procedures ~~referred to in Chapter X.X.~~ recommended by the OIE (under study); and

AND

2. all precautions have been taken to prevent infestation/contamination.

Article 9.4.9.

Recommendations for the importation of honey-bee collected pollen and beeswax (in the form of honeycomb)

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the products:

   EITHER

   a) comes from a country or *zone* free from *A. tumida* infestation; and

   b) contains no live honey bees or bee brood;

   OR

   c) contains no live honey bees or bee brood; and

   d) has been thoroughly cleaned, and treated to ensure the destruction of *A. tumida* spp., in conformity with one of the procedures ~~referred to in Chapter X.X.~~ recommended by the OIE (under study);

AND

2. all precautions have been taken to prevent infestation/contamination.

Article 9.4.10.

Recommendations for the importation of comb honey

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. comes from a country or *zone* free from *A. tumida* infestation; and

2. contains no live honey bees or bee brood;

OR

3. were subjected to a treatment at a temperature of -12°C or lower in the core of the product during at least 24 hours.

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CHAPTER 9.5.

TROPILAELAPS INFESTATION OF HONEY BEES

EU comment

The EU thanks the OIE TAHSC and can support the proposed changes.

However, comments are inserted in the text, to include another host species and for better consistence with the risk represented by "free apiaries" in non free country or zones.

Article 9.5.1.

General provisions

For the purposes of this Chapter, *Tropilaelaps* infestation of the honey bee *Apis mellifera* L. is caused by the mites *Tropilaelaps clareae*, *T. koenigerum*, *T. thaii* and *T. mercedesae*. The mite is an ectoparasite of brood of *Apis mellifera* L., *Apis laboriosa* and *Apis dorsata*, and cannot survive for periods of more than ~~7~~ 21 days away from bee brood.

EU comment

The words "*, Apis cerana*" should be added after "*Apis laboriosa*", since *A. cerana* is also a natural host of Tropilaelaps and can play an epidemiological role.

Early signs of *infection* normally go unnoticed, but the growth in the mite population is rapid leading to high hive mortality. The *infection* spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.5.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Tropilaelaps* status of the honey bee population of the *exporting country* or *zone.*

Article 9.5.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Tropilaelaps* infestation related conditions, regardless of the *Tropilaelaps* status of the honey bee population of the *exporting country* or *zone*:

1. honey bee semen, honey bee eggs and honey bee venom;

2. extracted honey, pollen, propolis, royal jelly for human consumption and processed beeswax ~~(not in the form of honeycomb)~~.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the *Tropilaelaps* status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.5.3.

Determination of the *Tropilaelaps* status of a country or zone~~/ compartment~~

The *Tropilaelaps* status of a country or *zone/~~compartment~~* ~~(under study)~~ can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for *Tropilaelaps* occurrence and their historic perspective;

2. *Tropilaelaps* infestation should be notifiable in the whole country or *zone/~~compartment~~* ~~(under study)~~ and all clinical signs suggestive of *Tropilaelaps* infestation should be subjected to field and laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of *Tropilaelaps* infestation;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.5.4.

Country or zone~~/compartment (under study)~~ free from *Tropilaelaps* spp

1. Historically free status

   A country or *zone/~~compartment~~* ~~(under study)~~ may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.5.3. but without formally applying a specific *surveillance* programme if the country or *zone/~~compartment~~* ~~(under study)~~ complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

   A country or *zone/~~compartment~~* ~~(under study)~~ which does not meet the conditions of point 1 above may be considered free from *Tropilaelaps* infestation after conducting a *risk assessment* as referred to in Article 9.5.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/~~compartment~~* ~~(under study)~~;

   b) *Tropilaelaps* infestation is notifiable in the whole country or *zone/~~compartment~~* ~~(under study)~~, and any clinical cases suggestive of *Tropilaelaps* infestation are subjected to field and laboratory investigations;

   c) for the 3 years following the last reported *case* of *Tropilaelaps* infestation, an annual survey supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/~~compartment~~* ~~(under study)~~ to provide a confidence level of at least 95% of detecting *Tropilaelaps* infestation if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;

   d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone/~~compartment~~* ~~(under study)~~ to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

   e) (under study) there is no self-sustaining feral population of *A. mellifera*, *A. dorsata* or *A. laboriosa*, or other possible host species in the country or *zone/~~compartment~~* ~~(under study)~~;

EU comment

The words ", *A. cerana*" should be added after "*A. dorsata*", since *A. cerana* is also a natural host of Tropilaelaps and can play an epidemiological role.

   f) the importation of the *commodities* listed in this Chapter into the country or *zone/~~compartment~~* ~~(under study)~~

is carried out, in conformity with the recommendations of this Chapter.

Article 9.5.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or ~~*zone/ compartment* (under study) officially~~ free from *Tropilaelaps* infestation or the apiary meets the conditions prescribed in Article 4.14.3.

EU comment

The risk represented by "free apiaries" according to article 4.14.3 in non free country or zones is higher than free countries or zones.

Thus, the following words should be added to the paragraph above:

"and a statistically valid number of animals were examined microscopically and found free from *Tropilaelaps* infestation."

Article 9.5.6.

Recommendations for the importation of live queen honey bees, worker bees and drones without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees have been held in isolation from brood and bees with access to brood, for a period of at least ~~7~~ 21 days.

EU comment

Even if the risk without brood combs is lower, the isolation alone is not sufficient, since the status of the exporting country/zone is not specified. Either the bees come from a free apiary, or they should be tested.

Thus, the following sentence should be added to the paragraph above:

"Bees should come from apiaries that meet the conditions prescribed in Article 4.14.3 or a statistically valid number of animals were examined microscopically and found free from *Tropilaelaps* infestation."

Article 9.5.7.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the equipment:

1. comes from a country or ~~*zone/ compartment* (under study)~~ free from *Tropilaelaps* infestation; or

2. contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least ~~7~~ 21 days prior to shipment; or

3. has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures ~~referred to in Chapter X.X.~~ recommended by the OIE (under study).

Article 9.5.8.

Recommendations for the importation of honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. come from a country or *~~zone/ compartment~~* ~~(under study)~~ free from *Tropilaelaps* infestation; or

2. contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least ~~7~~ 21 days prior to shipment; or

3. have been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures ~~referred to in Chapter X.X.~~ recommended by the OIE (under study).

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Annex XX (contd)

CHAPTER 9.6.

VARROOSIS OF HONEY BEES

EU comment

The EU thanks the OIE TAHSC and can support the proposed changes.

Article 9.6.1.

General provisions

For the purposes of this Chapter, varroosis is a *disease* of the honey bee *Apis mellifera* L. It is caused by the Korea and Japan haplotypes of the mite *Varroa destructor*, the original hosts of which are the Korea and Japan haplotypes of *Apis cerana* (under study). The mite is an ectoparasite of adults and brood of *Apis mellifera* L. During its life cycle, sexual reproduction occurs inside the honey bee brood cells. Early signs of *infection* normally go unnoticed, and only when *infection* is heavy does it become apparent. The *infection* spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

The number of parasites steadily increases with increasing brood activity and the growth of the bee population, especially late in the season when clinical signs of infestation can first be recognised. The life span of an individual mite depends on temperature and humidity but, in practice, it can be said to last from some days to a few months.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the varroosis status of the honey bee population of the *exporting country* or *zone.*

Article 9.6.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any varroosis related conditions, regardless of the varroosis status of the honey bee population of the *exporting country* or *zone*:

1. honey bee semen, honey bee eggs and honey bee venom;

2. extracted honey, pollen, propolis, royal jelly for human consumption and processed beeswax ~~(not in the form of honeycomb)~~.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the varroosis status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.6.3.

Determination of the varroosis status of a country or zone~~/ compartment~~

The varroosis status of a country or *zone~~/ compartment~~* ~~(under study)~~ can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for varroosis occurrence and their historic perspective;

2. varroosis should be notifiable in the whole country or *zone~~/compartment~~* ~~(under study)~~ and all clinical signs suggestive of varroosis should be subjected to field and laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of varroosis;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.6.4.

Country or zone~~/compartment (under study)~~ free from varroosis

1. Historically free status

A country or *zone~~/compartment~~* ~~(under study)~~ may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.6.3. but without formally applying a specific *surveillance* programme (historical freedom) if the country or *zone~~/compartment~~* ~~(under study)~~ complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or *zone~~/compartment~~* ~~(under study)~~ which does not meet the conditions of point 1 above may be considered free from varroosis after conducting a *risk assessment* as referred to in Article 9.6.3. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone~~/compartment~~* ~~(under study)~~;

b) varroosis is notifiable in the whole country or *zone~~/compartment~~* ~~(under study)~~, and any clinical cases suggestive of varroosis are subjected to field and laboratory investigations;

c) for the 3 years following the last reported *case* of varroosis, an annual survey supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone~~/compartment~~* ~~(under study)~~ to provide a confidence level of at least 95% of detecting varroosis if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of *disease*;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone~~/compartment~~* ~~(under study)~~ to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

e) (under study) there is no self-sustaining feral population of *A. mellifera*, the Korea and Japan haplotypes of *Apis cerana* or other possible host species in the country or *zone~~/compartment~~* ~~(under study)~~;

f) the importation of the *commodities* listed in this Chapter into the country or *zone~~/compartment~~* ~~(under study)~~ is carried out in conformity with the recommendations of this Chapter.

Article 9.6.4.bis

Apiary free from varroosis

1. The apiary is located in a country or zone complying with the requirements in points 2. a) b) and f) of Article 9.6.4.;

2. the apiary should be situated in an area with a radius of 50 kilometres in which no *case* of varroosis has been reported for at least the past 2 years; and

3. the apiary meets the conditions prescribed in Article 4.14.3.

Article 9.6.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/ ~~compartment~~* ~~(under study) officially~~ free from varroosis or the apiary meets the conditions prescribed in Article 9.6.4.bis.

Article 9.6.6.

Recommendations for the importation of larvae and pupae of honey bees

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. were sourced from a free country or *zone/ ~~compartment~~* ~~(under study)~~; or

2. have originated from queens in a *quarantine station* and were inspected and found free of *Varroa destructor*.

(wait for member comments to modify larvae and pupae articles)

Article 9.6.7.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the equipment:

1. comes from a country or *zone/ ~~compartment~~* ~~(under study)~~ free from varroosis; or

2. contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least ~~7~~ 21 days prior to shipment; or

3. has been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures ~~referred to in Chapter X.X.~~ recommended by the OIE (under study).

Article 9.6.8.

Recommendations for the importation of honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

Annex XX (contd)

1. come from a country or *zone/ ~~compartment~~* ~~(under study)~~ free from varroosis; or

2. contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least ~~7~~ 21 days prior to shipment; or

3. have been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures ~~referred to in Chapter X.X.~~ recommended by the OIE (under study).

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Annex XXI

CHAPTER 10.4.

AVIAN INFLUENZA

EU comment

The EU thanks the OIE TAHSC and can support the proposed changes.

Article 10.4.1.

General provisions

1. For the purposes of ~~*international trade*~~ the *Terrestrial Code*, avian influenza in its notifiable form (NAI) is defined as an *infection* of *poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):

   a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI;

   b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

2. *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

   Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

3. For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

~~3~~4. ~~For the purposes of *international trade*, t~~This chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of infection with NAI virus in the absence of clinical signs.

~~4. For the purposes of *international trade*, a Member should not impose immediate bans on the trade in *poultry commodities* in response to a notification, according to Article 1.2.3. of the *Terrestrial Code*, of infection with HPAI and LPAI virus in birds other than *poultry*, including wild birds.~~

5. Antibodies to H5 or H7 subtype of NAI virus, which have been detected in *poultry* and are not a consequence of vaccination, have to be immediately investigated. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough epidemiological and laboratory investigation that does not demonstrate further evidence of NAI infection.

6. The following defines the occurrence of infection with NAI virus:

   a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in *poultry* or a product derived from *poultry*; or

b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been detected in *poultry* or a product derived from *poultry*.

7. For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the *poultry* have shown no evidence of NAI infection, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

~~For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.~~

8. Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

9. A Member should not impose immediate bans on the trade in *poultry commodities* in response to a notification, according to Article 1.2.3. of the *Terrestrial Code*, of infection with HPAI and LPAI virus in birds other than *poultry*, including wild birds.

Article 10.4.2.

Determination of the NAI status of a country, zone or compartment

The NAI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, *laboratory* investigations;

2. appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in *poultry*, and the risk posed by birds other than *poultry*; this may be achieved through a NAI *surveillance* programme in accordance with Articles 10.4.27. to 10.4.33.;

3. consideration of all epidemiological factors for NAI occurrence and their historical perspective.

Article 10.4.3.

NAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI infection in *poultry* has been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, NAI free status can be regained:

1. In the case of HPNAI infections, 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

2. In the case of LPNAI infections, *poultry* may be kept for *slaughter* for human consumption subject to conditions specified in Article 10.4.19. or a *stamping-out policy* may be applied; in either case, 3 months after the *disinfection* of all affected *establishments*, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.4.

HPNAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from HPNAI when:

1. it has been shown that HPNAI infection in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown; or

2. when, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus.

The *surveillance* may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, HPNAI free status can be regained 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.5.

Recommendations for importation from a NAI free country, zone or compartment

for live poultry (other than day-old poultry)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* showed no clinical sign of NAI on the day of shipment;

2. the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;

3. the *poultry* are transported in new or appropriately sanitized *containers*;

4. if the *poultry* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry*;

2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* during the isolation period;

3. a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.29., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with a virus which would be considered NAI in *poultry*;

4. the birds are transported in new or appropriately sanitized *containers*;

Annex XXI (contd)

5. if the birds have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.7.

Recommendations for importation from a NAI free country, zone or compartment

for day-old live poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched;

2. the *poultry* were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the *poultry* are transported in new or appropriately sanitized *containers*;

4. if the *poultry* or the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.8.

Recommendations for importation from a HPNAI free country, zone or compartment

for day-old live poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* were kept in a HPNAI free country, *zone* or *compartment* since they were hatched;

2. the *poultry* were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the *poultry* are transported in new or appropriately sanitized *containers*;

4. if the *poultry* or the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. on the day of shipment, the birds showed no clinical signs of *infection* with a virus which would be considered NAI in *poultry*;

2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;

3. the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with NAIV;

4. the birds are transported in new or appropriately sanitized *containers*;

5. if the birds or parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.10.

Recommendations for importation from a NAI free country, zone or compartment

for hatching eggs of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from a NAI free country, *zone* or *compartment*;

2. the eggs were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the eggs are transported in new or appropriately sanitized packaging materials;

4. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.11.

Recommendations for importation from a HPNAI free country, zone or compartment

for hatching eggs of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from a HPNAI free country, *zone* or *compartment*;

2. the eggs were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

4. the eggs are transported in new or appropriately sanitized packaging materials;

5. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

Annex XXI (contd)

1. the parent *flock* birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from infection with NAIV;

2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

3. the eggs are transported in new or appropriately sanitized packaging materials;

4. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.13.

Recommendations for importation from a NAI free country, zone or compartment

for eggs for human consumption

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs were produced and packed in a NAI free country, *zone* or *compartment*;

2. the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.14.

Recommendations for importation from a HPNAI free country, zone or compartment

for eggs for human consumption

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs were produced and packed in a HPNAI free country, *zone* or *compartment*;

2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

3. the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.15.

Recommendations for importation of egg products of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from eggs which meet the requirements of Articles 10.4.13. or 10.4.14.; or

2. the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Article 10.4.25.;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.16.

Recommendations for importation from a NAI free country, zone or compartment

for poultry semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *poultry*:

1. showed no clinical sign of NAI on the day of semen collection;

2. were kept in a NAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.17.

Recommendations for the importation from a HPNAI free country, zone or compartment

for poultry semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *poultry*:

1. showed no clinical sign of HPNAI on the day of semen collection;

2. were kept in a HPNAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation of semen of birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;

2. showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* during the isolation period;

3. were tested within 14 days prior to semen collection and shown to be free of NAI infection.

Article 10.4.19.

Recommendations for importation from either a NAI or HPNAI free country, zone or compartment

for fresh meat of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *poultry*:

1. which have been kept in a country, *zone* or *compartment* free from HPNAI since they were hatched or for at least the past 21 days;

2. which have been slaughtered in an approved *abattoir* in a country, *zone* or *compartment* free from HPNAI and have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of NAI.

Annex XXI (contd)

Article 10.4.20.

Recommendations for the importation of meat products of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.4.19.; or

2. the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Article 10.4.26.;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.21.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from *poultry* which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.22.

Recommendations for the importation of feathers and down of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* originated from *poultry* as described in Article 10.4.19. and were processed in a NAI free country, *zone* or *compartment*; or

2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.23.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* have been processed to ensure the destruction of NAI virus (under study); and

2. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.24.

Recommendations for the importation of feather meal and poultry meal

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from *poultry* which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed either:

   a) with moist heat at a minimum temperature of 118ºC for minimum of 40 minutes; or

   b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122ºC for a minimum of 15 minutes; or

   c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74ºC;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.25.

Procedures for the inactivation of the AI virus in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of AI virus present in eggs and egg products:

	Core temperature (°C)	**Time**
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	513 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.26.

Procedures for the inactivation of the AI virus in meat

The following times for industry standard temperatures are suitable for the inactivation of AI virus present in *meat*.

	Core temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 seconds

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.27.

Surveillance: introduction

Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the *surveillance* for NAI complementary to Chapter 1.4., applicable to Members seeking to determine their NAI status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of NAI status is also provided.

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no Member can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in this chapter refers to the *infection* in *poultry* only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) infection is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NAIV infection.

Article 10.4.28.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* or NAI infection should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of NAI to a *laboratory* for NAI diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2. The NAI *surveillance* programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of NAI should be investigated immediately. As suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in NAI diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

   b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of *animals*, such as those adjacent to a NAI infected country, *zone* or *compartment*, places where birds and *poultry* of different origins are mixed, such as live bird markets, *poultry* in close proximity to waterfowl or other potential sources of NAIV.

An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is NAIV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NAIV infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.4.29.

Surveillance strategies

1. Introduction

   The target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*. Active and passive *surveillance* for NAI should be ongoing. The frequency of active *surveillance* should be at least every 6 months. *Surveillance* should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.

Annex XXI (contd)

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of NAIV infection at an acceptable level of confidence. Random *surveillance* is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results should be followed up with molecular or virological methods.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the NAI status of high risk populations.

A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NAIV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation, including *cases* of HPAI detected in any birds. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member wishes to declare freedom from NAIV infection in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease*/*infection* are technically well defined. The design of *surveillance* programmes to prove the absence of NAIV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of NAI at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory *disease* or a drop in egg production, is important for the early detection of NAIV infection. In some cases, the only indication of LPNAIV infection may be a drop in feed consumption or egg production.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should have restrictions imposed upon it until NAI infection is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of NAIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIV isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

3. Virological surveillance

Virological *surveillance* using tests described in the *Terrestrial Manual* should be conducted:

a) to monitor at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against NAIV. Positive NAIV antibody test results can have four possible causes:

a) natural *infection* with NAIV;

b) vaccination against NAI;

c) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to 4 weeks;

d) false positive results due to the lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for NAI *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of NAIV should not be compromised.

The discovery of clusters of seropositive *flocks* may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive *flocks* is always epidemiologically significant and therefore should be investigated.

If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to *infection* or vaccination should be employed.

The results of random or targeted serological surveys are important in providing reliable evidence that no NAIV infection is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

5. Virological and serological surveillance in vaccinated populations

The *surveillance* strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the *surveillance* strategy should be based on virological and/or serological methods and clinical *surveillance*. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate *laboratory* procedures are available. The interpretation of serological results in the presence of vaccination is described in Article 10.4.33.

Article 10.4.30.

Documentation of NAI or HPNAI free status

1. Members declaring freedom from NAI or HPNAI for the country, zone or compartment: additional surveillance procedures

In addition to the general conditions described in above mentioned articles, a Member declaring freedom from NAI or HPNAI for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Chapter, to demonstrate absence of NAIV or HPNAIV infection, during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated). This requires the support of a *laboratory* able to undertake identification of NAIV or HPNAIV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* may be targeted to *poultry* population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

2. Additional requirements for countries, zones or compartments that practise vaccination

Vaccination to prevent the transmission of HPNAI virus may be part of a *disease* control programme. The level of *flock* immunity required to prevent transmission will depend on the *flock* size, composition (e.g. species) and density of the susceptible *poultry* population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for NAI vaccines in the *Terrestrial Manual*. Based on the epidemiology of NAI in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other *poultry* subpopulations.

In all vaccinated *flocks* there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the vaccination programme should also be provided.

Article 10.4.31.

Countries, zones or compartments declaring that they have regained freedom from NAI or HPNAI following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring that it has regained country, *zone* or *compartment* freedom from NAI or HPNAI virus infection should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require *surveillance* incorporating virus detection and antibody tests described in the *Terrestrial Manual*. The use of sentinel birds may facilitate the interpretation of *surveillance* results.

A Member declaring freedom of country, *zone* or *compartment* after an *outbreak* of NAI or HPNAI (with or without vaccination) should report the results of an active *surveillance* programme in which the NAI or HPNAI susceptible *poultry* population undergoes regular clinical examination and active *surveillance* planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Article 10.4.32.

NAI free establishments within HPNAI free compartments: additional surveillance procedures

The declaration of NAI free *establishments* requires the demonstration of absence of NAIV infection. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the risk of *infection* and at a maximum interval of 21 days.

Article 10.4.33.

The use and interpretation of serological and virus detection tests

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus infection of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. *Poultry* vaccinated with inactivated whole AI vaccines containing an influenza virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In *poultry* vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. *Infection* is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. Vaccines used should comply with the standards of the *Terrestrial Manual*.

All *flocks* with seropositive results should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of NAI infection/circulation for each positive *flock*.

Annex XXI (contd)

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. The follow-up procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on NAI-vaccinated *poultry*. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated *animals*.

a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If *poultry* in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:

   i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection;

   ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins;

   iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

2. The follow-up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

The detection of antibodies indicative of a NAI virus infection as indicated in point a)i) above will result in the initiation of epidemiological and virological investigations to determine if the infections are due to HPNAI or LPNAI viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting *infection* by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic

cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field cases for *infection* by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

a) characterization of the existing production systems;

b) results of clinical *surveillance* of the suspects and their cohorts;

c) quantification of vaccinations performed on the affected sites;

d) sanitary protocol and history of the affected *establishments*;

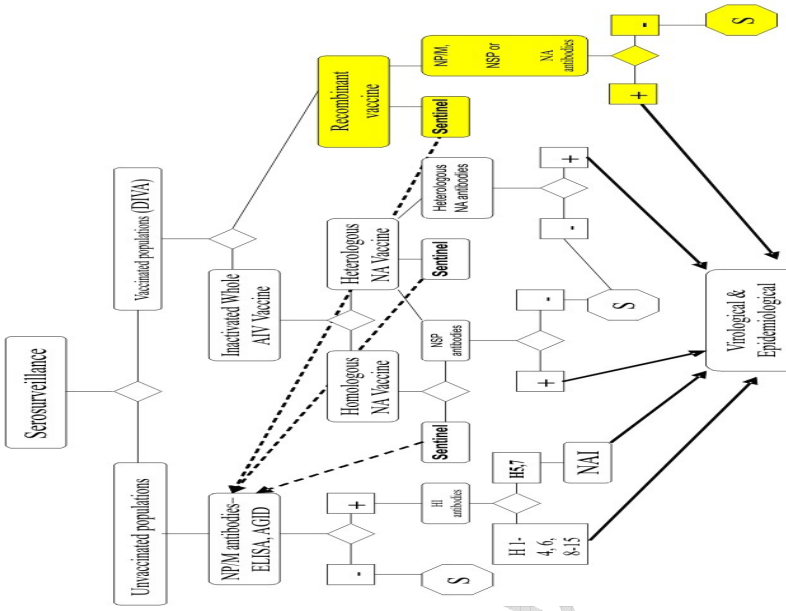
e) control of *animal identification* and movements;

f) other parameters of regional significance in historic NAIV transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological *surveillance* programme.

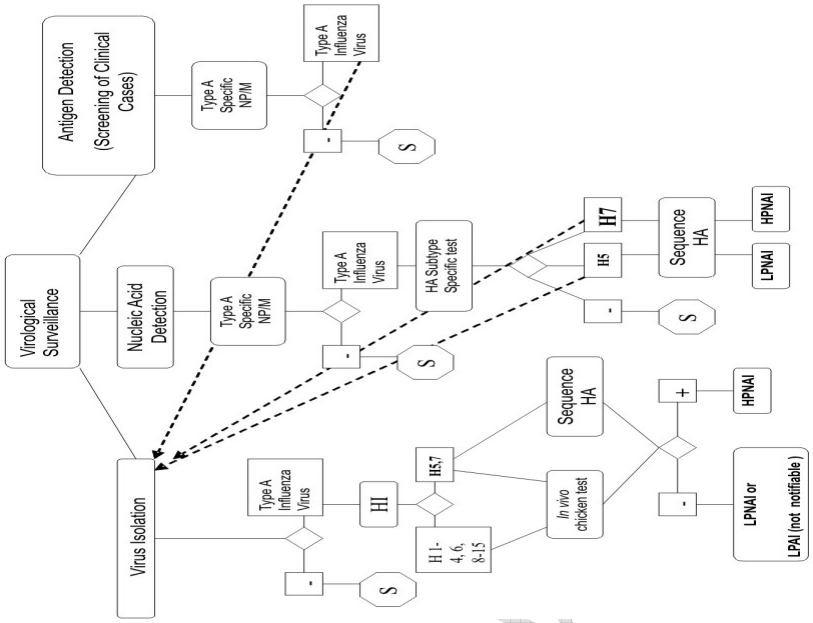
Annex XXI (contd)

Fig. 1. **Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys**



Key:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of NAIV

Fig. 2. **Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods**



The above diagrams indicate the tests which are recommended for use in the investigation of *poultry flocks*.

Key:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of NAIV

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Annex XXII

CHAPTER 10.13.

NEWCASTLE DISEASE

EU comment

The EU thanks the OIE TAHSC for the answers to its question and can support the proposed changes.

Article 10.13.1.

General provisions

1. For the purposes of ~~*international trade*~~ the *Terrestrial Code*, Newcastle disease (ND) is defined as an *infection* of *poultry* caused by a virus (NDV) of avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:

   a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallus gallus*) of 0.7 or greater; or

   b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

   In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.'

2. *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

   Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

3. For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.

~~3~~4. This chapter deals with NDV *infection* of *poultry* as defined in point 2 above, in the presence or absence of clinical signs. ~~For the purposes of *international trade*, a Member should not impose immediate bans on the trade in *poultry commodities* in response to a notification, according to Article 1.2.3. of the *Terrestrial Code*, of infection with NDV in birds other than *poultry*, including wild birds~~.

~~4~~5. The occurrence of infection with NDV is defined as the isolation and identification of NDV as such or the detection of viral RNA specific for NDV.

~~5. For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.~~

6. Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.

7. A Member should not impose immediate bans on the trade in *poultry commodities* in response to a notification, according to Article 1.2.3. of the *Terrestrial Code*, of infection with NDV in birds other than *poultry*, including wild birds.

Article 10.13.2.

Determination of the ND status of a country, zone or compartment

The ND status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. ND is notifiable in the whole country, an on-going ND awareness programme is in place, and all notified suspect occurrences of ND are subjected to field and, where applicable, *laboratory* investigations;

2. appropriate *surveillance* is in place to demonstrate the presence of NDV infection in the absence of clinical signs in *poultry*, this may be achieved through an ND *surveillance* programme in accordance with Articles 10.13.22. to 10.13.26.;

3. consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 10.13.3.

ND free country, zone or compartment

A country, *zone* or *compartment* may be considered free from ND when it has been shown that NDV *infection* in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.13.22. to 10.13.26.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.13.22. to 10.13.26. has been carried out during that three-month period.

Article 10.13.4.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.

for live poultry (other than day-old poultry)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* showed no clinical sign suggestive of ND on the day of shipment;

2. the *poultry* were kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;

3. the *poultry* are transported in new or appropriately sanitized *containers*;

4. if the *poultry* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.5.

Recommendations for the importation of live birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical sign suggestive of infection by NDV on the day of shipment;

2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* during the isolation period;

3. a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.13.24., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from infection with NDV;

4. the birds are transported in new or appropriately sanitized *containers*;

5. if the birds have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.6.

Recommendations for importation from an ND free country, zone or compartment

for day-old live poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* were hatched and kept in an ND free country, *zone* or *compartment* since they were hatched;

2. the *poultry* were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the *poultry* are transported in new or appropriately sanitized *containers*;

4. if the *poultry* or parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.7.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical sign suggestive of infection by NDV on the day of shipment;

2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;

3. the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from infection with NDV;

4. the birds are transported in new or appropriately sanitized *containers*;

5. if the birds or parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Annex XXII (contd)

Article 10.13.8.

Recommendations for importation from an ND free country, zone or compartment

for hatching eggs of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from an ND free country, *zone* or *compartment*;

2. the eggs were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the eggs are transported in new or appropriately sanitized packaging materials;

4. if the parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.9.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the parent *flock* birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from infection with NDV;

2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

3. the eggs are transported in new or appropriately sanitized packaging materials;

4. if the parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.10.

Recommendations for importation from an ND free country, zone or compartment

for eggs for human consumption

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs were produced and packed in an ND free country, *zone* or *compartment*;

2. the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.13.11.

Recommendations for importation of egg products of poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from eggs which meet the requirements of Article 10.13.10.; or

2. the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.13.20.;

AND

3. the necessary precautions were taken to avoid contact of the egg products with any source of NDV.

Article 10.13.12.

Recommendations for importation from an ND free country, zone or compartment

for poultry semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *poultry*:

1. showed no clinical sign suggestive of ND on the day of semen collection;

2. were kept in an ND free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.13.13.

Recommendations for the importation of semen of birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to and on the day of semen collection;

2. showed no clinical sign suggestive of infection with NDV during the isolation period and on the day of semen collection;

3. were subjected to a diagnostic test within 14 days prior to semen collection to demonstrate freedom from infection with NDV.

Article 10.13.14.

Recommendations for importation from an ND free country, zone or compartment

for fresh meat of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *poultry*:

1. which have been kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;

2. which have been slaughtered in an approved *abattoir* in an ND free country, *zone* or *compartment* and have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of ND.

Annex XXII (contd)

Article 10.13.15.

Recommendations for importation of meat products of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.13.14.; or

2. the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.13.21.;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.16.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.17.

Recommendations for the importation of feathers and down of poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* originated from *poultry* as described in Article 10.13.14. and were processed in a ND free country, *zone* or *compartment*; or

2. these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.18.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* have been processed to ensure the destruction of NDV (under study); and

2. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.19.

Recommendations for the importation of feather meal and poultry meal

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed either:

   a) with moist heat at a minimum temperature of 118ºC for minimum of 40 minutes; or

   b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122ºC for a minimum of 15 minutes; or

   c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74ºC for a minimum of 280 seconds;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of ND virus.

Article 10.13.20.

Procedures for the inactivation of the ND virus in eggs and egg products

The following times and temperatures are suitable for the inactivation of ND virus present in eggs and egg products:

	Core temperature (°C)	**Time**
Whole egg	55	2,521 seconds
Whole egg	57	1,596 seconds
Whole egg	59	674 seconds
Liquid egg white	55	2,278 seconds
Liquid egg white	57	986 seconds
Liquid egg white	59	301 seconds
10% salted yolk	55	176 seconds
Dried egg white	57	50.4 hours

Annex XXII (contd)

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.13.21.

Procedures for the inactivation of the ND virus in meat

The following times for industry standard temperatures are suitable for the inactivation of ND virus present in *meat*.

	Core temperature (°C)	**Time**
Poultry meat	65.0	840 seconds
	70.0	574 seconds
	74.0	280 seconds
	80.0	203 seconds

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.13.22.

Surveillance: introduction

Articles 10.13.22. to 10.13.26. define the principles and provide a guide on the *surveillance* for ND as defined in Article 10.13.1. and is complementary to Chapter 1.4. It is applicable to Members seeking to determine their ND status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of ND status is also provided.

Surveillance for ND is complicated by the known occurrence of avian paramyxovirus serotype 1 (APMV-1) infections in many bird species, both domestic and wild, and the widespread utilization of ND vaccines in domestic *poultry*.

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific recommendations for all situations. Therefore, *surveillance* strategies employed for demonstrating freedom from ND at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels, production systems and the commingling of different susceptible species require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member to provide scientific data that explains the epidemiology of ND in the region concerned and also demonstrates how all the risk factors are managed. There is, therefore, considerable latitude available to Members to provide a well-reasoned argument to prove freedom from NDV infection.

Surveillance for ND should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NDV infection.

Article 10.13.23.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular there should be in place:

   a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* or NDV *infection*;

   b) a procedure for the rapid collection and transport of samples from suspect cases of ND to a *laboratory* for ND diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data.

2. The ND *surveillance* programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of ND to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of ND should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in ND diagnosis and control;

   b) implement, when relevant, regular and frequent clinical, virological and serological *surveillance* of high risk groups of *poultry* within the target population (e.g. those adjacent to an ND infected country, *zone*, *compartment*, places where birds and *poultry* of different origins are mixed, or other sources of NDV).

An effective *surveillance* system may identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is due to NDV infection. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NDV infection should provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.13.24.

Surveillance strategies

1. Introduction

   Any *surveillance* programme requires inputs from professionals competent and experienced in this field and should be thoroughly documented. The design of *surveillance* programmes to prove the absence of NDV infection / circulation needs to be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

Annex XXII (contd)

If a Member wishes to declare freedom from NDV infection in a country, *zone* or *compartment*, the subpopulation used for the *surveillance* for the *disease* / *infection* should be representative of all *poultry* within the country, *zone* or *compartment*. Multiple *surveillance* methods should be used concurrently to accurately define the true ND status of *poultry* populations. Active and passive *surveillance* for ND should be ongoing with the frequency of active *surveillance* being appropriate to the disease situation in the country. *Surveillance* should be composed of random and/or targeted approaches, dependent on the local epidemiological situation and using clinical, virological and serological methods as described in the *Terrestrial Manual*. If alternative tests are used they should have been validated as fit-for-purpose in accordance with OIE standards. A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NDV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation.

In surveys, the sample size selected for testing should be statistically justified to detect *infection* at a predetermined target prevalence. The sample size and expected prevalence determine the level of confidence in the results of the survey. The survey design and frequency of sampling should be dependent on the historical and current local epidemiological situation. The Member should justify the choice of survey design and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in a population) may be an appropriate strategy.

It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. unvaccinated chickens). Similarly, virological and serological testing could target species that may not show clinical signs (Article 10.13.2.) of ND and are not routinely vaccinated (e.g. ducks). *Surveillance* may also target *poultry* populations at specific risk, for example direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live *poultry* markets, the presence of more than one species on the holding and poor biosecurity measures in place. In situations where wild birds have been shown to play a role in the local epidemiology of ND, *surveillance* of wild birds may be of value in alerting *Veterinary Services* to the possible exposure of *poultry* and, in particular, of free ranging *poultry*.

The sensitivity and specificity of the diagnostic tests are key factors in the choice of survey design, which should anticipate the occurrence of false positive and false negative reactions. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination / *infection* history and for the different species in the target population. If the characteristics of the testing system are known, the rate at which these false reactions are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The results of active and passive *surveillance* are important in providing reliable evidence that no NDV infection is present in a country, *zone* or *compartment*.

2. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs suggestive of ND at the *flock* level and should not be underestimated as an early indication of *infection*. Monitoring of production parameters (e.g. a drop in feed or water consumption or egg production) is important for the early detection of NDV infection in some populations, as there may be no, or mild clinical signs, particularly if they are vaccinated. Any sampling unit within which suspicious *animals* are detected should be considered as infected until evidence to the contrary is produced. Identification of infected *flocks* is vital to the identification of sources of NDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in a *laboratory*. This will enable the molecular, antigenic and other biological characteristics of the virus to be determined.

It is desirable that NDV isolates are sent promptly to an OIE Reference Laboratory for archiving and further characterization if required.

3. Virological surveillance

Virological *surveillance* should be conducted using tests described in the *Terrestrial Manual* to:

a) monitor at risk populations;

b) confirm suspect clinical *cases*;

c) follow up positive serological results in unvaccinated populations or sentinel birds;

d) test 'normal' daily mortalities (if warranted by an increased risk e.g. *infection* in the face of vaccination or in establishments epidemiologically linked to an *outbreak*).

4. Serological surveillance

Where vaccination is carried out, serological *surveillance* is of limited value. Serological *surveillance* cannot be used to discriminate between NDV and other APMV-1. Test procedures and interpretations of results are as described in the *Terrestrial Manual*. Positive NDV antibody test results can have five possible causes:

a) natural infection with APMV-1;

b) vaccination against ND;

c) exposure to vaccine virus;

d) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to 4 weeks;

e) non-specific test reactions.

It may be possible to use serum collected for other survey purposes for ND *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of NDV should not be compromised.

Discovery of seropositive, unvaccinated *flocks* should be investigated further by conducting a thorough epidemiological investigation. Since seropositive results are not necessarily indicative of *infection*, virological methods should be used to confirm the presence of NDV in such populations. Until validated strategies and tools to differentiate vaccinated *animals* from those infected with field APMV-1 are available, serological tools should not be used to identify NDV infection in vaccinated populations.

5. Use of sentinel poultry

There are various applications of the use of sentinel *poultry* as a *surveillance* tool to detect virus circulation. They may be used to monitor vaccinated populations or species which are less susceptible to the development of clinical *disease* for the circulation of virus. Sentinel *poultry* should be immunologically naïve and may be used in vaccinated *flocks*. In case of the use of sentinel *poultry*, the structure and organisation of the *poultry* sector, the type of vaccine used and local epidemiological factors will determine the type of production systems where sentinels should be placed, the frequency of placement and monitoring of the sentinels.

Sentinel *poultry* should be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel *poultry* should be observed regularly for evidence of clinical *disease* and any disease incidents investigated by prompt *laboratory* testing. The species to be used as sentinels should be proven to be highly susceptible to *infection* and ideally develop clear signs of clinical *disease*. Where the sentinel *poultry* do not necessarily develop overt clinical *disease* a programme of regular active testing by virological and serological tests should be used (the development of clinical *disease* may be dependent on the sentinel species used or use of live vaccine in the target population that may infect the sentinel *poultry*). The testing regime and the interpretation of the results will depend on the type of vaccine used in the target population. Sentinel birds should be used only if no appropriate *laboratory* procedures are available.

Article 10.13.25.

Documentation of ND free status: additional surveillance procedures

The requirements for a country, *zone* or *compartment* to declare freedom from ND are given in Article 10.13.3.

A Member declaring freedom of a country, *zone* or *compartment* (with or without vaccination) should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

1. Members declaring freedom from ND for the country, zone or compartment

   In addition to the general conditions described in the *Terrestrial Code*, a Member declaring freedom from ND for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The *surveillance* programme should be planned and implemented according to general conditions and methods described in this chapter to demonstrate absence of NDV infection in *poultry* during the preceding 12 months.

2. Additional requirements for countries, zones or compartments that practice vaccination

   Vaccination against ND may be used as a component of a disease prevention and control programme. The vaccine used should comply with the provisions of the *Terrestrial Manual*.

   In vaccinated populations there is a need to perform *surveillance* to ensure the absence of NDV circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The *surveillance* should be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*, or evidence to show the effectiveness of the vaccination programme is regularly provided.

Article 10.13.26.

Countries, zones or compartments regaining freedom from ND following an outbreak: additional surveillance procedures

A Member regaining country, *zone* or *compartment* freedom from ND should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*.

A Member declaring freedom of a country, *zone* or *compartment* after an *outbreak* of ND (with or without vaccination) should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

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Annex XXIII

CHAPTER 1.6.

STATUS FOR OIE LISTED DISEASES: PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

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EU comment

The EU can support the proposed change.

Article 1.6.5.

Questionnaire on contagious bovine pleuropneumonia

CBPP FREE COUNTRY

Report of a Member which applies for recognition of status, under Chapter 11.8. of the *Terrestrial Animal Health Code* (2010), as a CBPP free country

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to CBPP dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.

   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to CBPP.

   b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all CBPP related activities. Provide maps and tables wherever possible.

   c) Role of farmers, industry and other relevant groups in CBPP *surveillance* and control (include a description of training and awareness programmes on CBPP).

   d) Role of private veterinary profession in CBPP *surveillance* and control.

3. CBPP eradication

   a) History. Provide a description of the CBPP history in the country, date of first detection, origin of *infection*, date of eradication (date of last *case*).

b) Strategy. Describe how CBPP was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), and provide timeframe for eradication.

c) Vaccines and vaccination. Was CBPP vaccine ever used? If so, when was the last vaccination carried out?

d) Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. CBPP diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.4.9. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the CBPP approved laboratories, in particular to address the following points:

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

ii) Give details of participation in inter-laboratory validation tests (ring tests).

iii) Biosecurity measures applied.

iv) Details of the type of tests undertaken including procedures to isolate and identify *M.* mycoides subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with the provisions of Articles 11.8.12. to 11.8.17. of the *Terrestrial Code* and Chapter 2.4.9. of the *Terrestrial Manual.* In particular, the following points should be addressed:

a) Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

b) Slaughterhouses, *slaughter* slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

c) Provide details on training programmes for personnel involved in clinical and *slaughter* facilities *surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

d) For countries where a significant proportion of *animals* are not slaughtered in controlled *abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programmes, laboratory follow-up).

e) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds* of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

f) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

g) Provide a description of the means employed during the 2 years preceding this application to rule out the presence of any *Mmm*SC strain in the susceptible population. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

6. CBPP prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals*, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* for the past 2 years, specifying country or *zone* of origin, species and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- *animals*,
- semen, embryos and oocytes,
- veterinary medicinal products (i.e. biologics).

iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

Annex XXIII (contd)

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of CBPP.

b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?

c) In the event of a CBPP *outbreak*:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP;

iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken;

iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;

v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 11.8.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

a) no clinical CBPP has been detected for at least 2 years;

b) no CBPP vaccines have been used for at least 2 years in any susceptible species;

c) the country operates both clinical *surveillance* and *disease* reporting systems for CBPP adequate to detect clinical *disease* if it were present;

d) all clinical and pathological evidence suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;

e) there are effective measures in force to prevent the re-introduction of the *disease*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 11.8.4. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c), 5.b), 5.c) and 5.d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex XXIII (contd)

CBPP FREE ZONE

Report of a Member which applies for recognition of status, under Chapter 11.8. of the *Terrestrial Animal Health Code* (2010), as a CBPP free zone

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to CBPP dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above. The boundaries of the *zone* must be clearly defined. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to CBPP.

   b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all CBPP related activities. Provide maps and tables wherever possible.

   c) Role of farmers, industry and other relevant groups in CBPP *surveillance* and control (include a description of training and awareness programmes on CBPP).

   d) Role of private veterinary profession in CBPP *surveillance* and control.

3. CBPP eradication

   a) History. Provide a description of the CBPP history in the *zone*, date of first detection, origin of *infection*, date of eradication (date of last *case*).

   b) Strategy. Describe how CBPP was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out, zoning) and provide timeframe for eradication.

   c) Vaccines and vaccination. Was CBPP vaccine ever used? In the entire country? If vaccination was used, when was the last vaccination carried out? Where in the country?

   d) Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

   e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the *zone*? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

Annex XXIII (contd)

4. CBPP diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.4.9. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the CBPP approved laboratories, in particular to address the following points:

   i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

   ii) Give details of participation in inter-laboratory validation tests (ring tests).

   iii) Biosecurity measures applied.

   iv) Details of the type of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with the provisions of Articles 11.8.12. to 11.8.17. of the *Terrestrial Code* and Chapter 2.4.9. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

b) Slaughterhouses, *slaughter* slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

c) Provide details on training programmes for personnel involved in clinical and *slaughter* facilities *surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

d) For countries where a significant proportion of *animals* in the *zone* are not slaughtered in controlled *abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programme, laboratory follow-up).

e) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds* of each susceptible species are in the *zone*? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

f) Slaughterhouses and *markets*. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country and the *zone*? How are the *animals* transported and handled during these transactions?

g) Provide a description of the means employed during the 2 years preceding this application to rule out the presence of any *Mmm*SC strain in the susceptible population of the *zone*. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

6. CBPP prevention

a) Coordination with neighbouring countries and *zones*. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*. If the CBPP free *zone* is situated in a CBPP infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals*, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* for the past 2 years, specifying country or *zone* of origin, species and volume.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the *zone* and/or their final destination, concerning the import and follow-up of the following:

- *animals*,
- veterinary medicinal products (i.e. biologics).

iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of CBPP.

b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?

c) In the event of a CBPP *outbreak*:

i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP;

iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken;

iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;

v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 11.8.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating that in the *zone*:

a) no clinical CBPP has been detected for at least 2 years;

b) no CBPP vaccines have been used for at least 2 years in any susceptible species;

c) the country operates both clinical *surveillance* and *disease* reporting systems for CBPP adequate to detect clinical *disease* if it were present in the *zone*;

d) all clinical and pathological suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;

e) there are effective measures in force to prevent the re-introduction of the *disease*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 11.8.4. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c), 5.b), 5.c) and 5.d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

– text deleted

1. Accounts of the ages for eruption of the incisor teeth vary markedly and are clearly dependent on species, breed, nutritional status and nature of the feed. Therefore, for the purposes of serosurveillance, it should be noted that a) cattle having only one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffalos 24-48 months) and b) cattle having only two pairs of erupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffalos 48-60 months).

Annex XXIV

CHAPTER 11.12.

LUMPY SKIN DISEASE

(caused by group III virus, type Neethling)

EU comment

The EU thanks the OIE TAHSC and supports the proposed changes, but has some comments.

Article 11.12.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for lumpy skin disease (LSD) shall be 28 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 11.12.1.bis, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the LSD status of the cattle population of the *exporting country*.

Article 11.12.1.bis

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any LSD related conditions regardless of the LSD status of the cattle population of the *exporting country* or *zone*:

1. *milk* and *milk products*;

2. *meat* and *meat products*;

EU comment

The EU does not agree with the proposed new article as it stands. Indeed, the OIE disease card for LSD clearly states that the virus is found inter alia in milk, some internal organs and the lymph nodes, and that lesions could be found in subcutaneous adjacent muscles.

Thus there should be specific articles, including risk mitigation measures, for the importation of milk and meat from infected countries or zones.

Article 11.12.2.

LSD free country

A country may be considered free from LSD when:

1. LSD is notifiable in the country;

2. no *case* of LSD has been confirmed for at least the past 3 years.

3. no vaccination against LSD has been performed for at least 3 years

4. commodities have been imported in accordance with this Chapter.

EU comment

For consistency and clarity, the words "for at least 3 years" should be placed in the first line after the word "when" and consequently be deleted from points 2 and 3. And in the point 1 the word "is" should be replaced by "has been".

~~Article 11.12.3.~~

~~**Trade in commodities**~~

~~*Veterinary Authorities* of LSD free countries may prohibit importation or transit through their territory, from countries considered infected with LSD, of the following *commodities*:~~

~~1. domestic and wild *animals* of the bovine species;~~

~~2. semen of *animals* of the bovine species.~~

Article 11.12.4.

Recommendations for importation from LSD free countries

for domestic cattle

EU comment

The EU wishes to reiterate its comment on the use of the word "cattle". In the heading of the article 11.12.4, since Bubalis bubalis is susceptible to LSD, the word "cattle" should be replaced by "bovine". This comment is valid for articles 11.12.5 to 12.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of LSD on the day of shipment;
2. come from an LSD free country.

Article 11.12.5.

Recommendations for importation from LSD free countries

for wild cattle

EU comment

See comment above.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of LSD on the day of shipment;
2. come from an LSD free country;

if the country of origin has a common border with a country considered infected with LSD:

3. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.6.

Recommendations for importation from countries considered infected with LSD

for domestic cattle

EU comment

See comment above.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of LSD on the day of shipment;

2. either

a) were not vaccinated against LSD ~~during the 30~~ and were tested negative using tests according to the *Terrestrial Manual* within 14 days prior to shipment; or

3b. were vaccinated against LSD ~~not more than 3 months~~ between 30 days and 90 days prior to shipment;

AND

~~4~~3.

a. were kept since birth, or for the past 28 days, in an *establishment* where no *case* of LSD was officially reported during that period; or

~~5~~b. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.7.

Recommendations for importation from countries considered infected with LSD

for wild cattle

EU comment

See comment above.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of LSD on the day of shipment;

2. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.8.

Recommendations for importation from LSD free countries

for semen of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

    a. showed no clinical sign of LSD on the day of collection of the semen;

    b. were kept for at least 28 days prior to collection in an LSD free country;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.12.9.

Recommendations for importation from countries considered infected with LSD

for semen of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

   a. showed no clinical sign of LSD on the day of collection of the semen and for the following 28 days;

   b. were kept in the *exporting country* for the 28 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of LSD was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an LSD *infected zone*.

   c. and either

      i) were vaccinated against LSD between 28 days and 90 days before semen collection and thereafter vaccinated annually, or,

      ii) were tested with negative results using a serum neutralisation test (SNT) or an indirect enzyme-linked immunosorbent assay (ELISA) for LSD on the day of first semen collection or up to 90 days after last collection, or,

      iii) showed stable seropositivity (not more than a two-fold rise in titre) on paired samples (tested side by side) to indirect ELISA or SNT carried out in quarantine, 28-60 days apart, with the first sample taken on the day of first semen collection.

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.12.10.

Recommendations for importation from LSD free countries

for embryos/oocytes of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals* showed no clinical sign of LSD on the day of collection of the embryos/oocytes; and

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.12.11.

Recommendations for importation from countries considered infected with LSD

for embryos/oocytes of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

   a. were kept in an *establishment* where no *case* of LSD has been reported during the 28 days prior to collection; and

   b. showed no clinical sign of LSD on the day of collection;

   c. and either:

i. were vaccinated against LSD between ~~30~~ 28 days and 90 days before first embryo/oocyte collection and thereafter vaccinated annually; or

ii. were tested with negative results using a serum neutralisation test (SNT) or an indirect enzyme-linked immunosorbent assay (ELISA) for LSD on the day of embryo/oocyte collection or up to 90 days after last collection ~~according to the *Terrestrial Manual*~~; or

iii. showed ~~serostability~~ stable seropositivity (not more than a two-fold rise in titre) on paired samples (~~ to indirect ELISA tests,~~ tested side by side~~, carried out in isolation,~~) to indirect ELISA or SNT carried out in quarantine, ~~14~~28–60 days apart with one of the samples taken on the day of embryo/oocyte collection ~~of the embryos/oocytes~~;

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.12.12.

Recommendations for importation from LSD free countries

for products of animal origin (from cattle) intended for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in an LSD free country since birth or for at least the past 28 days.

Article 11.12.13.

Recommendations for importation from countries considered infected with LSD

for products of animal origin (from cattle) intended for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the LSD virus.

Article 11.12.14.

Recommendations for importation from countries considered infected with LSD

for raw hides of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products were stored for at least 40 days before shipment.

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- text deleted

Annex XXV

CHAPTER 12.1.

AFRICAN HORSE SICKNESS

EU comment

The EU could support the proposed changes.

However, some comments are inserted in the text in order to improve it.

Article 12.1.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for African horse sickness virus (AHSV) shall be 40 days for domestic horses. Although critical information is lacking for some species, this chapter applies to all equidae.

All countries or *zones* ~~neighbouring~~ adjacent to~~, or considered to be at risk from,~~ a country or *zone* not having free status should determine their AHSV status from an ongoing *surveillance* programme. Throughout the chapter, *surveillance* is in all cases understood as being conducted as described in ~~Chapter 1.4.~~ Article 12.11.1. to 12.1.13.

The following defines a *case* of AHS:

1. AHSV has been isolated and identified from an equid or a product derived from that equid; or

2. viral antigen or viral RNA specific to one or more of the serotypes of AHSV has been identified in samples from one or more equids showing clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed *case*; or

3. serological evidence of active infection with AHSV by detection of seroconversion with production of antibodies to structural or nonstructural proteins of AHSV that are not a consequence of vaccination have been identified in one or more equids that either show clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed *case.*

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual.*

Article 12.1.2.

AHSV free country or zone

1. A country or *zone* may be considered free from AHSV when African horse sickness (AHS) is notifiable in the whole country, systematic vaccination is prohibited, importation of equidae and their semen, oocytes or embryos are carried out in accordance with this chapter, and either:

   a) historical freedom as described in Chapter 1.4. has demonstrated no evidence of AHSV in the country or *zone*; or

   b) the country or *zone* has not reported any *case* of AHS for at least 2 years and is not adjacent to a country or *zone* not having a free status; or

   c) a *surveillance* programme has demonstrated no evidence of AHSV in the country or *zone* for at least 12 months and includes a complete season of *vector* activity; or

d) the country or *zone* has not reported any *case* of AHS for at least 40 days and a *surveillance* programme has demonstrated no evidence of *Culicoides* ~~likely to be competent AHSV *vectors*~~ for at least 2 years in the country or *zone*.

2. A AHS free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 12.1.11. to 12.1.13. *Animals* within this *zone* should be subjected to continuing *surveillance*. The boundaries of this *zone* should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to AHS transmission.

~~2~~3. An AHSV free country or *zone* will not lose its free status through the importation of vaccinated or seropositive equidae and their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.

4. To qualify for inclusion in the existing list of AHSV free countries or *zones*, a Member should:

a) have a record of regular and prompt animal disease reporting;

b) send a declaration to the OIE stating:

i) the section under paragraph 1 on the base of which the application is made;

ii) no systematic vaccination against AHS has been carried out during the past 12 months in the country or *zone*;

iii) equidae are imported in accordance with paragraph 3 above;

c. supply documented evidence that:

i) *surveillance* for both AHS and AHSV infection in accordance with Articles 12.1.11. to 12.1.13 is in operation;

ii) regulatory measures for the early detection, prevention and control of AHS have been implemented.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 4b)ii) and iii) and 4c) above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1., and in particular, formally state that :

1. there has been no *outbreak* of AHS during the past 12 months in the country or *zone*;

2. no evidence of AHSV infection has been found during the past 12 months in the country or *zone*.

Article 12.1.3.

AHSV seasonally free zone

1. An AHSV seasonally free *zone* is a part of an infected country or an *infected zone* in which for part of a year, ongoing *surveillance* and monitoring consistently demonstrated neither evidence of AHSV transmission nor the evidence of the presence of adult *Culicoides* ~~likely to be competent AHSV *vectors*~~.

2. For the application of Articles 12.1.6., 12.1.8. and 12.1.9., the seasonally free period is:

a) taken to commence the day following the last evidence of AHSV transmission and of the cessation of activity of adult *Culicoides* ~~likely to be competent AHSV *vectors*~~ as demonstrated by an ongoing *surveillance* programme, and

b) taken to conclude either:

i) at least 40 days before the earliest date that historical data show AHSV activity has recommenced; or

ii) immediately when current climatic data or data from a *surveillance* and monitoring programme indicate an earlier resurgence of activity of adult *Culicoides* ~~likely to be competent AHSV~~ *vectors*.

3. An AHSV seasonally free *zone* will not lose its free status through the importation of vaccinated or seropositive equidae and their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.

Article 12.1.4.

AHSV infected country or zone

For the purpose of this chapter, a~~A~~n AHSV infected country or ~~*infected*~~ *zone* is one that does not fulfil the requirements to qualified as either AHSV free country or zone or AHSV seasonally free zone ~~in which the conditions of Article 12.1.2. or Article 12.1.3. do not apply~~.

Article 12.1.4bis.

Establishment of a containment zone within an AHS free country or zone

EU comment

The establishment of a containment zone for a vector borne disease like AHS is difficult.

The containment zone should be large enough to contain any potentially infected vectors and the procedure should at least expressly include vector surveillance.

In the event of limited *outbreaks* within an AHS free country or *zone*, including within a *protection zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*. For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

1. the *outbreaks* are limited based on the following factors:

a) immediately on suspicion, a rapid response including notification has been made;

b) standstill of movements of equidae has been imposed, and effective controls on the movement of equidae and their products mentioned in this chapter are in place;

c) epidemiological investigation (trace-back, trace-forward) has been completed;

d) the *infection* has been confirmed;

e) the primary *outbreak* and likely source of the *outbreak* has been identified;

f) all *cases* have been shown to be epidemiologically linked;

g) no new *cases* have been found in the *containment zone* within a minimum of two *infectious periods* as defined in Article 12.1.1.;

2. the equidae within the *containment zone* should be clearly identifiable as belonging to the *containment zone*;

3. increased passive and targeted *surveillance* in accordance with Articles 12.1.11. to 12.1.13. has increased in the rest of the country or *zone* and has not detected any evidence of *infection*.

4. animal health measures that effectively prevent the spread of the AHS to the rest of the country or *zone*, taking into consideration the establishment of a *protection zone* within the *containment zone*, the seasonal vector conditions and existing physical, geographical and ecological barriers;

5. ongoing *surveillance* is in place in the *containment zone*;

The free status of the areas outside the *containment zone* is suspended pending the establishment of the *containment zone* in accordance with points 1 to 5 above. The free status of the areas outside the *containment zone* could be reinstated irrespective of the provisions of Article 12.1.4tris, once the *containment zone* is recognised by OIE.

The recovery of the AHS free status of the *containment zone* should follow the provisions of Article 12.1.4tris.

Article 12.1.4tris.

Recovery of free status

When an AHS *outbreak* occurs in an AHS free country or *zone*, the following waiting period is required to regain the status of AHS free country or *zone*:

1. 12 months after the last *case* and completion of the emergency vaccination and where *surveillance*, applied in accordance with Articles 12.1.11. to 12.1.13., has shown no evidence of AHSV infection; or

2. the conditions of Article 12.1.2. apply.

Article 12.1.5.

Recommendations for importation from AHSV free countries ~~that are neither neighbouring nor considered to be at risk from an AHSV infected country~~ or ~~infected~~ zones

for equidae

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of AHS on the day of shipment;

2. have not been vaccinated against AHS within the last 40 days;

3. were kept in an AHSV free country or zone since birth or for at least 40 days prior to shipment;

4. either:

   a) did not transit through an infected ~~country or *infected* zone~~ during transportation to the *place of shipment*; or

   b) were protected from attacks ~~by~~ from *Culicoides* at all times when transiting through an infected ~~country or *infected* zone~~.

Article 12.1.6.

Recommendations for importation from ~~AHSV free countries or free zones or from~~ AHSV seasonally free zones ~~(~~during the seasonally free period~~) that are neighbouring or are considered to be at risk from an AHSV infected country or infected zone~~

for equidae

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical signs of AHS on the day of shipment;

2. have not been vaccinated against AHS within the last 40 days;

3. and either

   a. were kept in an AHSV ~~free country, free *zone* or~~ seasonally free *zone* during the seasonally free period since birth or for at least 40 days prior to shipment; or

   ~~4~~b. ~~in a country or *zone* considered to be at risk~~, were held in ~~quarantine~~ isolation ~~for at least 40 days~~ prior to shipment and protected at all times from attacks by *Culicoides*~~; and~~

      ~~a~~i. for a period at least 28 days and a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *quarantine station*; or

      ~~b~~ii. for a period at least 40 days and serological tests according to the *Terrestrial Manual* to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the *quarantine station*; or

      ~~c~~iii. for a period at least 14 days and an agent identification test~~s~~ according to the *Terrestrial Manual* ~~were~~ was carried out with a negative result~~s~~ on a blood sample~~s~~ collected ~~on two occasions with an interval of~~ not less than 14 days ~~between collection, the first sample being collected at least 7 days~~ after introduction into the *quarantine station*;

EU Comment

The EU supports the replacement of the word "quarantine" by "isolation" in point b above. Thus, in points i, ii and iii the words "the quarantine station" should be replaced by "isolation".

~~5~~4. were protected from attacks ~~by~~ from *Culicoides* at all times ~~during transportation~~ ~~(including to and at the *place of shipment*)~~ when transiting through an infected *zone*.

Article 12.1.7.

Recommendations for importation from AHSV infected countries or zones

for equidae

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of AHS on the day of shipment;

2. have not been vaccinated against AHS within the last 40 days;

3. were held ~~continuously during the quarantine period of al least 40 days,~~ in a *vector-*~~proof~~ protected *quarantine station* and protected at all times from attacks by *Culicoides*; ~~and~~

   a) for a period at least 28 days and a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *quarantine station*; or

   b) for a period at least 40 days and serological tests according to the *Terrestrial Manual* to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the *quarantine station*; or

c) for a period at least 14 days and an agent identification tests according to the *Terrestrial Manual* were was carried out with a negative results on a blood samples collected on two occasions with an interval of not less than 14 days between collection, the first sample being collected at least 7 days after introduction into the *quarantine station*;

4. were protected from attacks by *Culicoides* at all times during transportation (including transportation to and at the *place of shipment*).

Article 12.1.8.

Recommendations for the importation of equid semen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;

2. had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;

3. were either:

   a) kept in an AHSV free country or free *zone* or from an AHSV seasonally free *zone* (during the seasonally free period) for at least 40 days before commencement of, and during collection of the semen, or

   b) kept in an AHSV free *vector* proof protected *artificial insemination centre* throughout the collection period, and subjected to either:

      i) a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group, carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of semen; or

      ii) agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every 7 days, during semen collection for this consignment.

Article 12.1.9.

Recommendations for the importation of *in vivo* derived equid embryos/oocytes

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

   a) showed no clinical sign of AHS on the day of collection of the embryos/oocytes and for the following 40 days;

   b) had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;

   c) were either:

      i) kept in an AHSV free country or free *zone* or from an AHSV seasonally free *zone* (during the seasonally free period) for at least 40 days before commencement of, and during collection of the embryos/oocytes, or

ii) kept in an AHSV free *vector*- ~~proof~~ protected *collection centre* throughout the collection period, and subjected to either:

- a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of embryos/oocytes; or

- agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every 7 days during embryos/oocytes collection for this consignment;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9., as relevant;

3. semen used to fertilize the oocytes, complies at least with the requirements in Article 12.1.8.

Article 12.1.10.

Protecting animals from *Culicoides* attack

1. Vector-protected establishment or facility

The means of protection of the *establishment* or facility should at least comprise the following:

a) double-door entry-exit system;

b) openings of the building are *vector* screened with mesh of appropriate aperture size (under study) impregnated regularly with an approved insecticide according to manufacturers' instruction;

EU comment

Even if the use of insecticides is a tool to prevent the vectors, its activity and environmental consequences should be carefully evaluated. The use of insecticide on mesh is useful to increase the level of insect protection but it must be evaluated (frequency, quantity, type of substance) in the light of the volume of the room, the number of animals present and the air circulation.

c) *vector surveillance* and control within and around the building;

EU comment

Vector surveillance within and outside stables is the key element for constantly verify the efficacy of the protection measures. However *vector* control is a very difficult task and, although some general recommendations may be given, no specific measures have proven effective in the past.

d) measures to limit breeding sites for *vectors* in vicinity of the *establishment* or facility;

e) Standard Operating Procedure, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of horses to the place of loading.

2. During transportation

When transporting equines through AHSV infected countries or AHSV *infected zones*, *Veterinary Authorities* should require strategies to protect animals from attacks by *Culicoides* during transport, taking into account the local ecology of the *vector*.

a) Transport by road:

Potential *risk management* strategies include a combination of:

~~1~~i. treating animals with chemical repellents prior to and during transportation, in sanitized *vehicles* treated with appropriate residual contact insecticide;

~~2~~ii. *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine and low temperature);

~~3~~iii. ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

~~4~~iv. darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shade cloth;

~~5~~v. monitoring for *vectors* at common stopping and offloading points to gain information on seasonal variations;

~~6~~vi. using historical, ongoing and/or AHS modelling information to identify low risk ports and transport routes.

b) Transport by air:

Prior to loading the equids, the crates, containers or jetstalls are sprayed with an insecticide approved in the country of dispatch.

Crates, containers or jet stalls in which equidae are being transported and the cargo hold of the aircraft must be sprayed with an approved insecticide just after the doors to the aircraft are closed and prior to takeoff.

In addition, during any stop over in countries or zones not free of AHS, prior to the opening of any aircraft door and until all doors are closed prior to takeoff, netting of appropriate aperture size (under study) impregnated with an approved insecticide must be placed over all crates, containers or jetstalls.

Article 12.1.11.

Surveillance: introduction

Articles 12.1.11. to 12.1.13. define the principles and provide a guide on the *surveillance* for AHS, complementary to Chapters 1.4. and 1.5. , applicable to Members seeking to determine their AHSV status. This may be for the entire country or *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of AHS status is also provided.

AHS is a *vector*-borne *infection* transmitted by a limited number of species of *Culicoides* insects. Unlike the related bluetongue virus, AHSV is so far geographically restricted to sub Saharan Africa with periodic excursions into North Africa, southwest Europe, the Middle East and adjacent regions of Asia. An important component of AHSV epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates *vector* competence, abundance, seasonal incidence, biting rates, survival rates and the extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context.

According to this chapter, a Member demonstrating freedom from AHSV infection for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of

the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter. This requires the support of a *laboratory* able to undertake identification of AHSV infection through the virus detection and antibody tests described in the *Terrestrial Manual*.

Susceptible captive wild, feral and wild equid populations should be included in the *surveillance* programme.

For the purposes of *surveillance*, a *case* refers to an equid infected with AHSV.

The purpose of *surveillance* is to determine if a country or *zone* is free from AHSV or if a *zone* is seasonally free from AHSV. *Surveillance* deals not only with the occurrence of clinical signs caused by AHSV, but also with evidence of infection with AHSV in the absence of clinical signs.

~~The following defines the occurrence of AHSV infection~~:

~~1. AHSV has been isolated and identified as such from an equid or a product derived from that equid, or~~

~~2. viral antigen or viral RNA specific to one or more of the serotypes of AHSV has been identified in samples from one or more equids showing clinical signs consistent with AHS, or epidemiologically linked to a confirmed or suspected *case*, or~~

~~3. serological evidence of active infection with AHSV by detection of seroconversion with production of antibodies to structural or nonstructural proteins of AHSV that are not a consequence of vaccination have been identified in one or more equids that either show clinical signs consistent with AHS, or epidemiologically linked to a suspected *case*.~~

Article 12.1.12.

Surveillance: general conditions and methods

1. A *surveillance* system should be under the responsibility of the *Veterinary Authority*. In particular the following should be in place:

   a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease*;

   b) a procedure for the rapid collection and transport of samples from suspect *cases* of AHS to a *laboratory* for AHS diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic, epidemiologic and *surveillance* data.

2. The AHS *surveillance* programme should:

   a) in a country/*zone*, free or seasonally free, include an early warning system for reporting suspicious *cases*. Persons who have regular contact with equids, as well as diagnosticians, should report promptly any suspicion of AHS to the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is AHS. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of AHS should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*;

   b) conduct random or targeted serological and virological *surveillance* appropriate to the *infection* status of the country or *zone* in accordance with Chapter 1.4.

Article 12.1.13.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* and/or *infection* should cover susceptible equids within the country or *zone*. Active and passive *surveillance* for AHSV infection should be ongoing. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the *infection* status of the country or *zone*.

A Member should justify the *surveillance* strategy chosen as appropriate to detect the presence of AHSV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. horses). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. donkeys).

In vaccinated populations serological and virological *surveillance* is necessary to detect the AHSV types circulating to ensure that all circulating types are included in the vaccination programme.

If a Member wishes to declare freedom from AHSV infection in a specific *zone*, the design of the *surveillance* strategy would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size, expected prevalence and diagnostic sensitivity of the tests determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence, in particular, needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles for *surveillance* for *disease*/*infection* are technically well defined. *Surveillance* programmes to prove the absence of AHSV infection/circulation, need to be carefully designed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

   Clinical *surveillance* aims at the detection of clinical signs of AHS in equids particularly during a newly introduced *infection*. In horses, clinical signs may include pyrexia, oedema, hyperaemia of mucosal membranes and dyspnoea.

   AHS suspects detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

   Serological *surveillance* of equid populations is an important tool to confirm absence of AHSV transmission in a country or *zone*. The species tested should reflect the local epidemiology of AHSV infection, and the equine species available. Management variables that may reduce the likelihood of *infection*, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the *surveillance* system.

Samples should be examined for antibodies against AHSV using tests prescribed in the *Terrestrial Manual*. Positive AHSV antibody tests results can have four possible causes:

a) natural *infection* with AHSV;

b) vaccination against AHSV;

c) maternal antibodies;

d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other purposes for AHSV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of AHSV infection should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no AHSV infection is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of AHSV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of AHSV, either random or targeted sampling is suitable to select *herds* and/or animals for testing.

Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV. An AHSV free country or *zone* may be protected from an adjacent infected country or *infected zone* by a *protection zone*.

Serological *surveillance* in *infected zones* will identify changes in the boundary of the *zone*, and can also be used to identify the AHSV types circulating. In view of the epidemiology of AHSV infection, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of AHSV from a proportion of infected animals is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* using tests described in the *Terrestrial Manual* can be conducted:

a) to identify virus circulation in at risk populations;

b) to confirm clinically suspect *cases*;

c) to follow up positive serological results;

d) to better characterize the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They comprise groups of unexposed equids that are not vaccinated and are managed at fixed locations and observed and sampled regularly to detect new AHSV infections.

The primary purpose of a sentinel equid programme is to detect AHSV infections occurring at a particular place, for instance sentinel groups may be located on the boundaries of *infected zones* to detect changes in distribution of AHSV. In addition, sentinel equid programmes allow the timing and dynamics of *infections* to be observed.

A sentinel equid programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of AHSV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting AHSV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors sentinel groups should comprise animals selected to be of similar age and susceptibility to AHSV infection. The only feature distinguishing groups of sentinels should be their geographical location. Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling should reflect the equid species used and the reason for choosing the sampling site. In endemic areas virus isolation will allow monitoring of the serotypes and genotypes of AHSV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of *infection*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that AHSV infections are not occurring unobserved. Here sampling prior to and after the possible period of transmission is sufficient.

Definitive information on AHSV circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required sentinels should be sampled at sufficiently frequent intervals to ensure that some samples are collected during the period of viraemia.

5. Vector surveillance

AHSV is transmitted between equine hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of *vector surveillance* is to define high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread. Long term *surveillance* can also be used to assess *vector* abatement measures.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to equids.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel animals is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare. Other *surveillance* strategies are preferred to detect virus circulation.

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CHAPTER 1.6.

STATUS FOR OIE LISTED DISEASES: PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

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Article 1.6.6.

Questionnaire on African horse sickness

AHS FREE COUNTRY

Report of a Member which applies for recognition of status, under Chapter 12.1. of the *Terrestrial Animal Health Code* (2010), as a AHS free country

Please address concisely the following topics. National legislation, regulations and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a. Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to AHS introduction. Provide a map identifying the factors above.

   b. Equine sector. Provide a general description of the equine sector and their relative economic importance in the country. Outline significant changes observed (if relevant documents are available, please attach).

      i. Sport and race horses

      ii. Breeding stock equidae

      iii. Working and production equidae (including horses for slaughter)

      iv. Leisure equidae

      v. Captive wild, wild and feral equidae

2. Description of equid population

   a. Demographics of domestic equidae. What is the equidae population by species within the various sectors? Provide a description of the methods of animal identification, holding and individual animal registration systems if in place. How are they distributed (e.g. density, etc.)? Provide tables and maps as appropriate.

   b. Wildlife demographics. What captive wild, wild or feral equidae are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and captive wild, wild or feral equidae?

Annex XXV (contd)

3. Veterinary system

   a. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to AHS.

   b. Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all AHS related activities. Provide maps and tables wherever possible.

   c. Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS *surveillance* and control (include a description of training and awareness programmes on AHS).

   d. Role of private veterinary profession in AHS *surveillance* and control.

4. AHS eradication

   a. History. Provide a description of the AHS history in the country if applicable, date of first detection, origin of *infection*, date of eradication (date of last *case*), and serotypes present.

   b. Strategy. Describe how AHS was controlled and eradicated (e.g. isolation of cases, *stamping-out policy*, zoning), provide time frame for eradication.

   c. Vaccines and vaccination. What type of vaccine was used? What equine species were vaccinated? Were vaccinated animals marked or was vaccination recorded in a unique identification document?

   d. Legislation, organisation and implementation of the AHS eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines were used and give a brief summary.

   e. Animal identification. Are equidae identified (individually or at a group level)?

   f. Movements of equidae. How are movements of equidae controlled in the country? Provide evidence on the effectiveness of equidae identification and movement controls. Please provide information on pastoralism, transhumance and related movements.

   g. Leisure and competition movements of equidae. How are movements of competition and leisure equidae controlled in the country. Please provide information on systems including any use of registration. Provide information on any events that include international movements of equidae.

   h. Describe the market systems for equidae, in particular, if markets require the international movement of equidae.

5. AHS diagnosis

   Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.5.1. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

   a. Is AHS laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.

   b. Provide an overview of the AHS approved laboratories, in particular to address the following points:

      i. Details on the types of tests undertaken.

ii. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO that exist in, or planned for, the laboratory system.

iii. Give details of participation in inter-laboratory validation tests (ring tests).

iv. Describe biosecurity measures applied, particularly in the case where live virus is handled.

6. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the country complies with the provisions of Articles 12.1.11. to 12.1.13. of the *Terrestrial Code*, and Chapter 2.5.1. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a. Clinical suspicion. What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom), is there a compensation system in place and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for AHS, species, type of sample, testing method(s) and results (including differential diagnosis).

b. Surveillance. Are the following undertaken?

i. Serological surveillance

ii. Virological surveillance

iii. Sentinel animals

iv. Vector surveillance

If so, provide detailed information on the survey designs. How frequently are they conducted? Which were the equine species included? Are wildlife species included? Provide a summary table indicating detailed results, for at least the past 2 years. Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of equidae examined and samples tested. Provide details on the methods selected and applied for monitoring the performance of the *surveillance* system.

7. AHS prevention

a. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that have been taken into account (e.g. size, distance from adjacent border to infected equidae)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

If the AHS free country borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent and/or vectors, taking into consideration the seasonal vector conditions and existing physical, geographical and ecological barriers.

b. Import control procedures

From what countries or *zones* does the country authorize the import of equidae or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such equidae and products, and subsequent internal movement? What import conditions (e.g. quarantine) and test procedures are required? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports, temporary admissions or re-entry of equidae and their products for at least the past 2 years, specifying country or *zone* of origin and volume.

Annex XXV (contd)

i. Provide a map with the number and location of ports, airports and land crossings. Is the service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the *Competent Authority*. Describe the communication systems between the *Competent Authority* and the border inspection posts, and between border inspection posts.

ii. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- Equidae,
- genetic material (semen, ova and embryos of the equine species),
- equine derived (by-)products and biological.

iii. Describe the action available under legislation, and actually taken, when an illegal introduction is detected. Provide information on detected illegal introduction.

8. Control measures and contingency planning

a. Give details of any written guidelines, contingency plans (including information on vaccine banks) available to the *Competent Authority* for dealing with suspected or confirmed *cases* of AHS.

b. In the event of a suspected or confirmed AHS *outbreak*:

i. is quarantine imposed on premises with suspicious *cases*, pending final diagnosis?

ii. are movement restrictions applied on suspicion?

iii. describe the sampling and testing procedures used to identify and confirm presence of the causative agent;

iv. describe the actions taken to control the disease situation in and around any holdings found to be infected with AHS;

v. describe the control and/or eradication procedures (e.g. vaccination, modified stamping-out,;

vi. describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including conditions for restocking;

vii. give details of any compensation made available when equidae are killed, for *disease* control/eradication purposes.

9. Compliance with the *Terrestrial Code*

a. In addition to the documentary evidence that the provisions of Article 12.1.2 are properly implemented and supervised, the Delegate of the country must submit a declaration stating:

i. The section under paragraph 1 (of Article 12.1.2.) on the base of which the application is made;

ii. there has been no *outbreak* of AHS during the past 12 months;

iii. no systematic vaccination against AHS has been carried out during the past 12 months;

b. and that vaccinated equidae were imported in accordance with Chapter 12.1.

10. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 12.1.2. of the *Terrestrial Code* and provide detailed information as specified in sections 4(a), b), c and 6, and highlight any measures introduced to prevent a recurrence of the infection under section 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

AHS FREE ZONE

Report of a Member which applies for recognition of status, under Chapter 12.1. of the *Terrestrial Animal Health Code* (2010), as a AHS free zone

Please address concisely the following topics. National legislation, regulations and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

a. Geographical factors. Provide a general description of the country and the zone including physical, geographical and other factors that are relevant to AHS introduction. Provide a map identifying the factors above. The boundaries of the zone must be clearly defined, including a protection zone, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone (and of the protection zone) established in accordance with Chapter 4.3.

b. Equine sector. Provide a general description of the equine sector and their relative economic importance in the country and the zone. Outline significant changes observed (if relevant documents are available, please attach).

i. Sport and race horses

ii. Breeding stock equidae

iii. Working and production equidae (including horses for slaughter)

iv. Leisure equidae

v. Captive wild, wild and feral equidae

2. Description of equidae population

a. Demographics of domestic equidae. What is the equidae population by species within the various sectors in the country and the zone? Provide a description of the methods of animal identification, holding and individual animal registration systems in the country and the zone if in place. How are they distributed (e.g. density, etc.)? Provide tables and maps as appropriate.

b. Wildlife demographics. What captive wild, wild or feral equidae are present in the country and the zone? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and captive wild, wild or feral equidae?

Annex XXV (contd)

3. Veterinary system

   a. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to AHS.

   b. Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all AHS related activities in the country and in the zone. Provide maps and tables wherever possible.

   c. Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS *surveillance* and control (include a description of training and awareness programmes on AHS).

   d. Role of private veterinary profession in AHS *surveillance* and control.

4. AHS eradication

   a. History. Provide a description of the AHS history in the country and zone, if applicable, date of first detection, origin of *infection*, date of eradication in the zone (date of last *case*), and serotypes present.

   b. Strategy. Describe how AHS was controlled and eradicated in the zone (e.g. isolation of cases, *stamping-out policy*, zoning), provide time frame for eradication.

   c. Vaccines and vaccination. What type of vaccine was used in the zone and the rest of the country? What equine species were vaccinated? Were vaccinated animals marked or was vaccination recorded in a unique identification document?

   d. Legislation, organisation and implementation of the AHS eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines were used and give a brief summary.

   e. Animal identification. Are equidae identified (individually or at a group level)?

   f. Movements of equidae. How are movements of equidae controlled in, and between zones of the country? Provide evidence on the effectiveness of equidae identification and movement controls in the zone. Please provide information on pastoralism, transhumance and related ~~paths of~~ movements.

   g. Leisure and competition movements of equidae. How are movements of competition and leisure equidae controlled in the country and the zones. Please provide information on systems including any use of registration. Provide information on any events that include international movements of equidae.

   h. Describe the market systems for equidae in the country and the zones, in particular, if markets require the international movement of equidae.

5. AHS diagnosis

   Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.5.1. of the *Terrestrial Manual* are applied in the country and the zone. In particular, the following points should be addressed:

   a. Is AHS laboratory diagnosis carried out in the country and the zone? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory (ies) where samples originating from the zone are diagnosed.

   b. Provide an overview of the AHS approved laboratories, in particular to address the following points:

i. Details on the types of tests undertaken.

ii. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO that exist in, or planned for, the laboratory system.

iii. Give details of participation in inter-laboratory validation tests (ring tests).

iv. Describe biosecurity measures applied, particularly in the case where live virus is handled.

6. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the zone complies with the provisions of Articles 12.1.11. to 12.1.13. of the *Terrestrial Code*, and Chapter 2.5.1. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a. Clinical suspicion. What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom), is there a compensation system in place and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for AHS, species, type of sample, testing method(s) and results (including differential diagnosis) from the zone.

b. Surveillance. Are the following undertaken?

i. Serological surveillance

ii. Virological surveillance

iii. Sentinel animals

iv. Vector surveillance

If so, provide detailed information on the survey designs. How frequently are they conducted? Which were the equine species included? Are wildlife species included? Provide a summary table indicating detailed results, for at least the past 2 years. Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of equidae examined and samples tested. Provide details on the methods selected and applied for monitoring the performance of the *surveillance* system.

7. AHS prevention

a. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and/or *zones* that have been taken into account (e.g. size, distance from adjacent border to infected equidae)? Describe coordination, collaboration and information sharing activities with neighbouring countries and zones.

If the AHS free zone is established in an AHS infected country or borders an infected country or zones, describe the animal health measures implemented to effectively prevent the introduction of the agent and/or vectors, taking into consideration the seasonal vector conditions and existing physical, geographical and ecological barriers.

Annex XXV (contd)

b. Import control procedures. From what countries or *zones* does the country authorize the import of equidae or their products into the free zone? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such equidae and products, and subsequent internal movement? What import conditions (e.g. quarantine) and test procedures are required? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports, temporary admissions or re-entry of equidae and their products to the free zone for at least the past 2 years, specifying country or *zone* of origin and volume.

   i. Provide a map with the number and location of ports, airports and land crossings in the zone. Is the service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the *Competent Authority*. Describe the communication systems between the *Competent Authority* and the border inspection posts, and between border inspection posts.

   ii. Describe the regulations, procedures, type and frequency of checks at the points of entry into the zone and/or their final destination, concerning the import and follow-up of the following:

      - Equidae,

      - genetic material (semen, ova and embryos of the equine species),

      - equine derived (by-)products and biologicals,

   iii. Describe the action available under legislation, and actually taken, when an illegal introduction into the zone is detected. Provide information on detected illegal introductions into the zone.

8. Control measures and contingency planning

   a. Give details of any written guidelines, contingency plans (including information on vaccine banks) available to the *Competent Authority* for dealing with suspected or confirmed *cases* of AHS in the country and the zone (including the protection zone if applicable).

   b. In the event of a suspected or confirmed AHS *outbreak* in the zone:

      i. is quarantine imposed on premises with suspicious *cases*, pending final diagnosis?

      ii. are movement restrictions applied on suspicion?

      iii. describe the sampling and testing procedures used to identify and confirm presence of the causative agent;

      iv. describe the actions taken to control the disease situation in and around any holdings found to be infected with AHS;

      v. describe the control and/or eradication procedures (e.g. vaccination, modified stamping-out;

      vi. describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including conditions for restocking;

      vii. give details of any compensation made available when equidae are killed, for *disease* control/eradication purposes.

9. Compliance with the Terrestrial Code

   a. In addition to the documentary evidence that the provisions of Article 12.1.2 are properly implemented and supervised, the Delegate of the country must submit a declaration stating:

      i. The section under paragraph 1 (of Article 12.1.2.) on the base of which the application is made

      ii. there has been no *outbreak* of AHS during the past 12 months in the zone;

      iii. no systematic vaccination against AHS has been carried out during the past 12 months in the zone;

   b. and that vaccinated equidae were imported into the zone in accordance with Chapter 12.1.

10. Recovery of status

    Countries applying for recovery of status should comply with the provisions of Article 12.1.2. of the *Terrestrial Code* and provide detailed information as specified in sections 4 (a), (b), (c) and 6 and highlight any measures introduce to prevent a recurrence of the infection under Section 7 of this questionnaire.

CHAPTER 12.6.

EQUINE INFLUENZA

EU comment

The EU thanks the OIE and supports the proposed changes.

Article 12.6.1.

General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic horses, donkeys and mules.

~~For the purposes of *international trade*, t~~This chapter deals not only with the occurrence of clinical signs caused by equine influenza virus (EIV), but also with the presence of infection with EIV in the absence of clinical signs.

For the purposes of this chapter, isolation is defined as 'the separation of domestic equids from domestic equids of a different equine influenza health status, utilising appropriate biosecurity measures, with the purpose of preventing the transmission of *infection*'.

For the purposes of the *Terrestrial Code*, the *infective period* for EI 21 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual.*

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.7.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the *exporting country*, *zone* or *compartment*.

Article 12.6.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any EIV related conditions, regardless of the EI status of the equine population of the *exporting country*, *zone* or *compartment*:

1. semen;

2. *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant (under study).

Article 12.6.3.

Determination of the EI status of a country, a zone or a compartment

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for EI occurrence and their historic perspective;

2. whether EI is notifiable in the whole country, an on-going EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, *laboratory* investigations;

3. appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in domestic equids.

Article 12.6.4.

EI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from EI provided the *disease* is notifiable in the whole country and it shows evidence, through an effective *surveillance* programme, planned and implemented according to the general principles in Chapter 1.4., that no *case* of EI occurred in the past 2 years.

The *surveillance* may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, movements of equids within and into the country, *zone* or *compartment*, wild equid populations or proximity to recent *outbreaks*.

A country, *zone* or *compartment* seeking freedom from EI, in which vaccination is practised, should also demonstrate that EIV has not been circulating in the population of domestic and wild equidsae during the past 12 months, through *surveillance*, in accordance with Chapter 1.4.

In a country in which vaccination is not practised, *surveillance* may be conducted using serological testing alone. In countries where vaccination is practised, the *surveillance* should include agent identification methods described in the *Terrestrial Manual* for evidence of *infection*.

A country, *zone* or *compartment* seeking freedom from EI should apply appropriate movement controls to minimise the risk of introduction of EIV in accordance with this chapter.

If an *outbreak* of clinical EI occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical *case*, providing that *surveillance* for evidence of *infection* has been carried out during that twelve-month period in accordance with Chapter 1.4.

Article 12.6.5.

Recommendations for the importation of domestic equids for immediate slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic equids showed no clinical sign of EI on the day of shipment.

Article 12.6.6.

Recommendations for the importation of domestic equids for unrestricted movement

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic equids:

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its vaccination status should be included in the veterinary certificate;

OR

2. came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

3. were immunised according to the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual* between 21 and 90 days before shipment either with a primary course or a booster; information on their vaccination status should be included in the veterinary certificate.

For additional security, countries that are free of EI or undertaking an eradication programme may also request that the domestic equids were tested negative for EIV by an agent identification test for EI described in the *Terrestrial Manual* conducted on samples collected on two occasions at 7 to 14 days and less than 5 days before shipment.

Article 12.6.7.

Recommendations for the importation of domestic equids which will be kept in isolation (see Article 12.6.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic equids:

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its vaccination status should be included in the veterinary certificate;

OR

2. showed no clinical sign of EI in any premises in which the domestic equids had been resident for the 21 days prior to shipment nor on the day of shipment; and

3. were immunised according to the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual*; information on their vaccination status should be included in the veterinary certificate.

Article 12.6.8.

Recommendations for the importation of fresh meat of equids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from equids which had been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.

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CHAPTER 12.9.

EQUINE VIRAL ARTERITIS

EU comment

The EU thanks the TAHSCV and supports the proposed changes.

Article 12.9.1.

General provisions

The *infective period* for equine viral arteritis (EVA) shall be 28 days for all categories of equine except sexually mature stallion where the *infective period* may be for the life of the *animal*. Because the *infective period* may be extended in the case of virus shedding in semen, the status of seropositive stallions should be checked to ensure that they do not shed virus in their semen.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 12.9.2.

Recommendations for the importation of uncastrated male equines

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment and met one of the following requirements:

1. were isolated for the 28 days prior to shipment and were subjected, to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a single blood sample collected during the 21 days prior to shipment with negative result; or

2. were subjected between 6 and 9 months of age to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

3. met the following requirements:

   a) were isolated; and

   b) not earlier than 7 days of commencing isolation were ~~tested, with negative results, with~~ subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results; and

EU Comment

The word "results" should be "result".

   c) were then immediately vaccinated; and

   d) were kept separated from other equidae for 21 days following vaccination; and

   e) were revaccinated regularly according to the manufacturer's instructions; or

4. have been subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a blood sample with positive results and then: either

a) were subsequently test mated to two mares within 6 months prior to shipment which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or

b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected during the 6 months prior to shipment;

c) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within 6 months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly.

Article 12.9.3.

Recommendations for the importation of equines other than uncastrated males

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of EVA on the day of shipment and were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to shipment; and

EITHER

1. were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to shipment; and

   a) were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on blood samples collected on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or

   b) were regularly vaccinated according to the manufacturer's instructions;

OR

2. were isolated for the 28 days prior to shipment and during this period the *animals* showed no signs of EVA.

Article 12.9.4.

Recommendations for the importation of semen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the animal donors were kept for the 28 days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period and showed no clinical sign of EVA on the day of semen collection; and

1. were subjected between 6 and 9 months of age to a test for EVA as prescribed in the *Terrestrial Manual* on two blood samples collected at least 14 days apart with a stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

2. were isolated and not earlier than 7 days of commencing isolation were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated according to the manufacturer's instructions; or

3. were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equidae not of an equivalent EVA status for 14 days prior to blood sampling ~~from the time of the taking of the blood sample~~ until the end of semen collection; or

4. have been subjected to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample with positive results and then: either

   a) were subsequently test mated to two mares within 6 months prior to semen collection, which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the test mating, or

   b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within 6 months prior to collection of the semen to be exported; or

   c) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within 6 months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly; or

5. were, for frozen semen, subjected with negative results either:

   a) to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample taken not earlier than 14 days and not later than 12 months after the collection of the semen for export; or

   b) to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* carried out on an aliquot of the semen collected immediately prior to processing or on an aliquot of semen collected within 14 to 30 days after the first collection of the semen to be exported.

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Annex XXVI

CHAPTER 14.5.

CHLAMYDOPHILA ABORTUS INFECTION

(ENZOOTIC ABORTION OF EWES, (OVINE CHLAMYDIOSIS)

EU comment

The EU can support the proposed changes.

The EU encourages the OIE TAHSC to align the title of all disease chapters on this example, i.e.:

"*Name of agent* infection / infestation (Common name(s) of disease)"

Article 14.5.1.

General provisions

For the purposes of the *Terrestrial Code*, enzootic abortion of ewes (EAE), also known as ovine chlamydiosis or ovine enzootic abortion, is an infection of domestic sheep and goats by the bacterium *Chlamydophila abortus*.

~~For the purposes of the *Terrestrial Code*, the following information should be considered with regard to the *incubation period* for enzootic abortion of ewes (EAE).~~ Susceptible *animals* become infected through ingestion of infectious materials. In lambs and non-pregnant ewes, the *infection* remains latent until conception. Ewes exposed to *infection* late in pregnancy may not exhibit signs of *infection* until the subsequent pregnancy. Countries should take account of these risk factors.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 14.5.2.

Recommendations for the importation of sheep and/or goats for breeding

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. have remained since birth, or for the previous 2 years, in *establishments* where no EAE has been diagnosed during the past 2 years;

2. showed no clinical sign of EAE on the day of shipment;

3. were subjected to a diagnostic test for EAE with negative results within the 30 days prior to shipment.

Article 14.5.3.

Sheep flocks and/or goat herds free from EAE infection

To qualify as free from EAE *infection*, a sheep *flock* or goat *herd* shall satisfy the following requirements:

1. it is under official veterinary *surveillance*;

2. all sheep and goats showed no clinical evidence of EAE *infection* during the past 2 years;

3. a statistically valid number of sheep and goats over 6 months of age were subjected to a diagnostic test for EAE with negative results within the past 6 months;

4. all sheep or goats are permanently identified;

5. no sheep or goat has been added to the *flock* or *herd* since 30 days prior to the *flock* or *herd* test referred to in point 3 above unless:

   a) either the additions were isolated from other members of the *flock* or *herd* in the *establishment* of origin for a minimum period of 30 days and then were subjected to a diagnostic test for EAE with negative results, before entry into the new *flock* or *herd*; or

   b) they originated from an *establishment* of equal health status.

Article 14.5.4.

Recommendations for the importation of semen of sheep

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

   a) have been kept in *establishments* or *artificial insemination centres* free from EAE during the past 2 years, and have not been in contact with *animals* of a lower health status;

   b) were subjected to a diagnostic test for EAE with negative results 2 to 3 weeks after collection of the semen;

2. an aliquot of the semen to be exported was shown to be free of ~~*Chlamydia psittaci*~~ *Chlamydophila abortus*, by culture techniques.

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Annex XXVII

CHAPTER 14.9.

SCRAPIE

EU comment

The EU thanks the OIE TAHSC for the clarification in article 14.9.1 and for the change in article 14.9.4.

The EU will continue monitoring atypical Scrapie in order to gather more data on this condition.

Article 14.9.1.

General provisions and safe commodities

Scrapie is a neurodegenerative *disease* of sheep and goats. The main mode of transmission is from mother to offspring immediately after birth and to other susceptible neonates exposed to the birth fluids and tissues of an infected *animal*. Transmission occurs at a much lower frequency to adults exposed to the birth fluids and tissues of an infected *animal*. A variation in genetic susceptibility of sheep has been recognised. The *incubation period* of the *disease* is variable; however, it is usually measured in years. The duration in *incubation period* can be influenced by a number of factors including host genetics and strain of agent.

Scrapie is not considered to pose a risk to human health. The recommendations in this chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in sheep and goats. The chapter ~~does not cover~~ excludes so-called 'atypical' scrapie ~~which~~ because this condition is clinically, pathologically, biochemically and epidemiologically unrelated to 'classical' scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep.

1. When authorising import or transit of the following *commodities* derived from sheep or goats and any products made from these *commodities* and containing no other tissues from sheep or goats, *Veterinary Authorities* should not require any scrapie-related conditions, regardless of the scrapie risk status of the sheep and goat populations of the *exporting country*, *zone* or *compartment*:

   a) *in vivo* derived sheep embryos handled in accordance with Chapter 4.7. of this *Terrestrial Code*;

   b) *meat* (excluding materials as referred to in Article 14.9.12.);

   c) hides and skins;

   d) gelatine;

   e) collagen prepared from hides or skins;

   f) tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

   g) dicalcium phosphate (with no trace of protein or fat);

   h) wool or fibre.

2. When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the scrapie risk status of the sheep and goat populations of the *exporting country*, *zone* or *compartment*.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 14.9.2.

Determination of the scrapie status of the sheep and goat populations of a country, zone, compartment or establishment

The scrapie status of the sheep and goat populations of a country, *zone*, *compartment* or *establishment* should be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for scrapie occurrence and their historic perspective, in particular the:

    a) importation or introduction of sheep and goats or their semen, *in vivo* derived goat embryos or *in vitro* processed sheep and goat embryos/oocytes potentially infected with scrapie;

    b) extent of knowledge of the population structure and husbandry practices of sheep and goats;

    c) feeding practices, including consumption of *meat-and-bone meal* or *greaves* derived from ruminants;

    d) importation of *milk* and *milk products* of sheep or goats origin intended for use in feeding of sheep and goats;

2. an on-going awareness programme for *veterinarians*, farmers, and workers involved in transportation, marketing and *slaughter* of sheep and goats to facilitate recognition and encourage reporting of all *animals* with clinical signs compatible with scrapie;

3. a *surveillance* and monitoring system including the following:

    a) official veterinary *surveillance*, reporting and regulatory control in accordance with the provisions of Chapter 1.4.;

    b) a *Veterinary Authority* with current knowledge of, and authority over, all *establishments* which contain sheep and goats in the whole country;

    c) compulsory notification and clinical investigation of sheep and goats showing clinical signs compatible with scrapie;

    d) examination, in accordance with the *Terrestrial Manual*, in a *laboratory* of appropriate material from sheep and goats older than 18 months displaying clinical signs compatible with scrapie;

    e) maintenance of records including the number and results of all investigations for at least 7 years.

Article 14.9.3.

Scrapie free country or zone

Countries or *zones* may be considered free from scrapie if within the said territory:

1. a *risk assessment*, as described in point 1 of Article 14.9.2., has been conducted, and it has been demonstrated that appropriate measures are currently in place and have been taken for the relevant period of time to manage any *risk* identified and points 2 and 3 have been complied with for the preceding 7 years;

AND

2. one of the following conditions should be met:

    a) the country or the *zone* have demonstrated historical freedom as follows:

i) scrapie has been notifiable for at least 25 years; and

ii) a formal programme of targeted *surveillance* and monitoring, which includes testing of sheep and goats displaying clinical signs compatible with scrapie and those over 18 months of age slaughtered, culled or found dead on farm, can be documented as having been in place for at least 10 years; and

iii) appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and

- either scrapie has never been reported; or

- no *case* of scrapie has been reported for at least 25 years;

b) for at least 7 years, sheep and goats displaying clinical signs compatible with scrapie have been tested. Also a sufficient number of sheep and goats over 18 months of age, representative of slaughtered, culled or found dead on farm, have been tested annually, to provide a 95% level of confidence of detecting scrapie if it is present in that population at a prevalence rate exceeding 0.1% and no *case* of scrapie has been reported during this period; or

c) all *establishments* containing sheep or goats have been accredited free as described in Article 14.9.5.;

AND

3. the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country for at least 7 years;

AND

4. introductions of sheep and goats or their semen, *in vivo* derived goat embryos or *in vitro* processed sheep and goat embryos/oocytes from countries or *zones* not free from scrapie are carried out in accordance with Articles 14.9.6., 14.9.7., 14.9.8. or 14.9.9., as relevant.

Article 14.9.4.

Compartment free from scrapie

To qualify as a *compartment* free from scrapie, all sheep and goats in a *compartment* should be certified by the *Veterinary Authority* as satisfying the following requirements:

1. all *establishments* within the *compartment* are free from scrapie according to Article 14.9.5.;

2. all *establishments* within the *compartment* are managed under a common *biosecurity plan* protecting them from introduction of scrapie, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.;

3. introductions of sheep and goats are allowed only from ~~accredited~~ free *establishments* or free countries;

4. introductions of *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos/oocytes are allowed either from ~~accredited~~ free *establishments* or in accordance with Article 14.9.9.;

5. sheep and goat semen should be introduced into the *compartment* in accordance with Article 14.9.8.;

6. sheep and goats in the *compartment* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* not within the *compartment*.

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Article 14.9.5.

Scrapie free establishment

To qualify as free from scrapie, an *establishment* of sheep and goats should satisfy the following requirements:

1. in the country or *zone* where the *establishment* is situated, the following conditions are fulfilled:

   a) the *disease* is compulsorily notifiable;

   b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;

   c) affected sheep and goats are killed and completely destroyed;

   d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country for at least 7 years;

   e) an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;

2. in the *establishment* the following conditions have been complied with for at least 7 years:

   a) sheep and goats are permanently identified and records maintained, to enable trace back to their *establishment* of birth;

   b) records of movements of sheep and goats in and out of the *establishment* are maintained;

   c) introductions of sheep and goats are allowed only from free *establishments* or *establishment* at an equal or higher stage in the process of accreditation;

   d) introduction of *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos /oocytes should comply with Article 14.9.9.;

   e) sheep and goat semen should be introduced into the *establishment* in accordance with Article 14.9.8.;

   f) an *Official Veterinarian* inspects sheep and goats in the *establishments* and audits the records at least once a year;

   g) no *case* of scrapie has been reported;

   h) sheep and goats of the *establishments* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* of a lower status;

   i) all culled sheep and goats over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting wasting signs and all those exhibiting neurological signs are tested in a *laboratory* for scrapie. The selection of the sheep and goats to be tested should be made by the *Official Veterinarian*. Sheep and goats over 18 months of age that have died or have been killed for reasons other than routine *slaughter* should also be tested (including 'fallen' stock and those sent for emergency *slaughter*).

Article 14.9.6.

Recommendations for importation from countries or zones not considered free from scrapie

for sheep and goats for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals* come from an *establishment* free from scrapie as described in Article 14.9.5.

Article 14.9.7.

Recommendations for importation from countries or zones not considered free from scrapie

for sheep and goats for slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:
    a) the *disease* is compulsorily notifiable;
    b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
    c) affected sheep and goats are killed and completely destroyed;
2. the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

Article 14.9.8.

Recommendations for importation from countries or zones not considered free from scrapie

for semen of sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
    a) are permanently identified to enable trace back to their *establishment* of origin;
    b) showed no clinical sign of scrapie at the time of semen collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 14.9.9.

Recommendations for importation from countries or zones not considered free from scrapie

for *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos/oocytes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:
    a) the *disease* is compulsorily notifiable;
    b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
    c) affected sheep and goats are killed and completely destroyed;
    d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country;

Annex XXVII (contd)

2. the donor *animals* either have been kept since birth in a free *establishment*, or meet the following conditions:

   a) are permanently identified to enable trace back to their *establishment* of origin;

   b) have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;

   c) showed no clinical sign of scrapie at the time of embryo/oocyte collection;

3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 14.9.10.

Recommendations for importation from countries or zones not considered free from scrapie

for milk and milk products of sheep or goat origin intended for use in feeding of sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *milk* and *milk products* come from scrapie free *establishments*.

Article 14.9.11.

Recommendations on meat-and-bone meal

Meat-and-bone meal containing any sheep or goat protein, or any feedstuffs containing that type of *meat-and-bone meal*, which originate from countries not considered free of scrapie should not be traded between countries for ruminant feeding.

Article 14.9.12.

Recommendations for importation from countries or zones not considered free from scrapie

for skulls including brains, ganglia and eyes, vertebral column including ganglia and spinal cord, tonsils, thymus, spleen, intestine, adrenal gland, pancreas, or liver, and protein products derived therefrom, from sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* should not be traded for use in ruminant feeds;

2. for purposes other than ruminant feeding, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

   a) in the country or *zone*:

      i) the *disease* is compulsorily notifiable;

      ii) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;

      iii) affected sheep and goats are killed and completely destroyed;

   b) the materials come from sheep and goats that showed no clinical sign of scrapie on the day of *slaughter*.

Article 14.9.13.

Recommendations for the importation of ovine and caprine materials destined for the preparation of biologicals

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products originate from sheep and goats born and raised in a scrapie free country, *zone* or *establishment*.

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Annex XXVIII

CHAPTER 15.2.

CLASSICAL SWINE FEVER

EU comment

The EU commends the OIE for the improvement of the articles on surveillance and can support the proposed changes.

Article 15.2.1.

General provisions

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between domestic pig and wild pig (including feral pigs) populations.

EU comment

The EU supports the new definitions for wild animals as this will help clarify the definition of diseases like CSF. In the second sentence of the new paragraph above, in order to take into account the reality of the epidemiology of the disease, the words "between domestic pig and wild pig (including feral pigs) populations" should be replaced by the words "between domestic pig and captive wild pig populations on the one hand, and wild pigs and feral pig populations on the other hand."

For the purposes of ~~*international trade*~~ the *Terrestrial Code*, classical swine fever (CSF) is defined as an *infection* of domestic pigs.

EU comment

For the same reason as above, the words "domestic pigs" should be replaced by "domestic and captive wild pigs".

Domestic pig is defined as 'all domesticated pigs, permanently captive or farmed free range, used for the production of *meat* for consumption, for the production of other commercial products or for breeding these categories of pigs.

~~The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between domestic pig and wild pig (including feral pigs) populations.~~

Pigs exposed to CSF virus prenatally may be persistently infected throughout life and may have an *incubation period* of several months before showing signs of *disease*. Pigs exposed postnatally have an *incubation period* of 2-14 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic *infections*.

~~For the purposes of *international trade*, a Member should not impose trade bans in response to a notification of infection with classical swine fever virus in wild pigs according to Article 1.2.3. of the *Terrestrial Code* after the Member confirms that Article 15.2.2. is appropriately implemented.~~

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

A Member should not impose trade bans in response to a notification of infection with classical swine fever virus in wild pigs according to Article 1.2.3. of the *Terrestrial Code* after the Member confirms that Article 15.2.2. is appropriately implemented.

Article 15.2.2.

Determination of the CSF status of a country, zone or compartment

The CSF status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

1. CSF should be notifiable in the whole territory, and all clinical signs suggestive of CSF should be subjected to appropriate field and/or *laboratory* investigations;

2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;

3. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment*;

4. the *Veterinary Authority* should have current knowledge about the population and habitat of wild pigs in the country or *zone*;

5. for domestic pigs, appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, and the risk posed by wild pigs, is in place; this may be achieved through a *surveillance* programme in accordance with Articles 15.2.23. to 15.2.28.;

6. for wild pigs, if present in the country or *zone*, a *surveillance* programme is in place according to Article 15.2.28., taking into account the presence of natural and artificial boundaries, the ecology of the wild pig population, and an assessment of the risks of *disease* spread.

7. Based on the assessed risk of spread within the wild pig population, and according to Article 15.2.26., the domestic pig population should be separated from the wild pig population by appropriate biosecurity measures to prevent transmission of CSF from wild to domestic pigs.

Article 15.2.3.

CSF free country, zone or compartment

A country, *zone* or *compartment* may be considered free from CSF when *surveillance* in accordance with Articles 15.2.23. to 15.2.28. has been in place for at least 12 months, and when:

1. there has been no *outbreak* of CSF in domestic pigs during the past 12 months;

2. no evidence of CSFV infection has been found in domestic pigs during the past 12 months;

3. no vaccination against CSF has been carried out in domestic pigs during the past 12 months unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;

4. imported domestic pigs comply with the requirements in Article 15.2.5. or Article 15.2.6.

EU comment

Article 15.2.26 describes not only surveillance measures but also biosecurity measures. In the first sentence of the article 15.2.3 above, the words "*and biosecurity*" should be added after "*surveillance*".

Article 15.2.4.

Recovery of free status

Should a CSF *outbreak* occur in a free country, *zone* or *compartment*, the free status may be restored where *surveillance* in accordance with Articles 15.2.23. to 15.2.28. has been carried out with negative results either:

1. 3 months after the last *case* where a *stamping-out policy* without vaccination is practised;

OR

2. where a *stamping-out policy* with emergency vaccination is practised:

   a) 3 months after the last *case* and the *slaughter* of all vaccinated *animals*, or

   b) 3 months after the last *case* without the *slaughter* of vaccinated *animals* where there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;

OR

3. where a *stamping-out policy* is not practised, the provisions of Article 15.2.3. should be followed.

Article 15.2.5.

Recommendations for importation from countries, zones or compartments free of CSF

for domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of CSF on the day of shipment;

2. were kept in a country, *zone* or *compartment* free of CSF since birth or for at least the past 3 months;

3. have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.2.6.

Recommendations for importation from CSF infected countries or zones

for domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of CSF on the day of shipment;

2. were kept since birth or for the past 3 months in a CSF free *compartment*;

3. have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

EU comment

This article should be deleted as it is superfluous: the import from a free compartment is already covered by 15.2.5.

Article 15.2.7.

Recommendations for the importation of wild pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of CSF on the day of shipment;

2. were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;

3. have not been vaccinated against CSF, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.2.8.

Recommendations for importation from countries, zones or compartments free of CSF

for semen of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

    a) were kept in a country, *zone* or *compartment* free of CSF since birth or for at least 3 months prior to collection;

    b) showed no clinical sign of CSF on the day of collection of the semen;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.2.9.

Recommendations for importation from CSF infected countries or zones

for semen of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:

    a) were kept in a *compartment* free of CSF since birth or for at least 3 months prior to collection;

    b) showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;

    c) met one of the following conditions:

        i) have not been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection, with negative results; or

        ii) have been vaccinated against CSF and were subjected to a serological test in accordance with the *Terrestrial Manual* performed at least 21 days after collection and it has been conclusively demonstrated that any antibody is due to the vaccine; or

        iii) have been vaccinated against CSF and were subjected to a virological test performed in accordance with the *Terrestrial Manual* on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.2.10.

Recommendations for importation from countries, zones or compartments free of CSF

for *in vivo* derived embryos of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females showed no clinical sign of CSF on the day of collection of the embryos;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 15.2.11.

Recommendations for importation from CSF infected countries or zones

for *in vivo* derived embryos of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

    a) were kept in a *compartment* free of CSF since birth or for at least 3 months prior to collection;

    b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 40 days;

    c) and either:

        i) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; or

        ii) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated by means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), that any antibody is due to the vaccine;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 15.2.12.

Recommendations for importation from countries, zones or compartments free of CSF

for fresh meat of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *animals* which:

1. have been kept in a country, *zone* or *compartment* free of CSF, or which have been imported in accordance with Article 15.2.5. or Article 15.2.6.;

2. have been slaughtered in an approved *abattoir*, have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of CSF.

Article 15.2.13.

Recommendations for the importation of fresh meat of wild pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that ~~the entire consignment of *fresh meat* comes from *animals*~~:

1. the entire consignment of *fresh meat* comes from *animals* which have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre, and have been found free of any sign suggestive of CSF;

2. where the CSF-free status of the wild pig population cannot be assured, the entire consignment of meat comes from *animals* from each of which a sample has been collected and has been subjected to a virological test and a serological test for CSF, with negative results.

EU comment

The words "entire consignment of" above are superfluous and should be deleted. On the certificate, which always refers to one specific consignment, the words "the meat" are sufficient and self explanatory.

Article 15.2.14.

Recommendations for the importation of meat and meat products of pigs, or for products of animal origin (from fresh meat of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. have been prepared:

   a) exclusively from *fresh meat* meeting the conditions laid down in Article 15.2.12.;

   b) in a processing establishment:

      i) approved by the *Veterinary Authority* for export purposes;

      ii) processing only *meat* meeting the conditions laid down in Article 15.2.12.;

OR

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 15.2.21. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.15.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in accordance with Article 15.2.20. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.16.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for agricultural or industrial use

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.17.

Recommendations for the importation of bristles

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.18.

Recommendations for the importation of litter and manure

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.19.

Recommendations for the importation of skins and trophies

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 15.2.22. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.20.

Procedures for the inactivation of the CSF virus in swill

For the inactivation of CSF viruses likely to be present in swill, one of the following procedures should be used:

1. the swill should be maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or

2. the swill should be maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar.

Article 15.2.21.

Procedures for the inactivation of the CSF virus in meat

For the inactivation of viruses present in *meat*, one of the following procedures should be used:

1. Heat treatment

   Meat shall be subjected to one of the following treatments:

   a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more;

   b) heat treatment at a minimum temperature of 70°C, which should be reached throughout the *meat*.

2. Natural fermentation and maturation

   The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

   a) an aw value of not more than 0.93, or

   b) a pH value of not more than 6.0.

   Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

3. Dry cured pork meat

   a) Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.

   b) Spanish style pork *meat* with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

Article 15.2.22.

Procedures for the inactivation of the CSF virus in skins and trophies

For the inactivation of CSF viruses likely to be present in skins and trophies, one of the following procedures should be used:

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;

2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3. soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate - Na2CO3) maintained at pH 11.5 or above for at least 48 hours;

4. soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5. in the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate - Na2CO3).

Article 15.2.23.

Surveillance: introduction

Articles 15.2.23. to 15.2.28. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Members seeking to determine their CSF status. This may be for the entire country, ~~or~~ a *zone* or a *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of CSF status is also provided.

The impact and epidemiology of CSF differ widely in different regions of the world, and it is, therefore, impossible to provide specific recommendations for all situations. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach should be tailored in order to prove freedom from CSF for a country or *zone* where wild pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent countries. The method should examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Members to provide a well-reasoned argument to prove that absence of classical swine fever virus (CSFV) infection is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that a population in a country, *zone* or *compartment* is free from CSFV infection or to detect the introduction of CSFV into a population already recognized as free. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on *disease* spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent *infections*, the occurrence of persistent and chronic *infections*, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serological cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serological surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

For the purposes of this chapter, virus *infection* means presence of CSFV as demonstrated directly by virus isolation, the detection of virus antigen or virus nucleic acid, or indirectly by seroconversion which is not the result of vaccination.

Article 15.2.24.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. ~~A procedure should be in place for the rapid collection and transport of samples to an accredited *laboratory* as described in the *Terrestrial Manual*.~~

   a) formal and ongoing system for detecting and investigating *outbreaks of disease* or CSFV infection should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of CSF to a laboratory for CSF diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and surveillance data should be in place.

2. The CSF *surveillance* programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers, who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of CSF to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated employing clinical, pathological, and *laboratory* diagnosis. ~~This requires that sampling kits and other equipment are available to those responsible for *surveillance*.~~ Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;

b) implement, when relevant, regular and frequent clinical inspections and serological testing of high-risk groups of *animals* (for example, where swill feeding is practised), or those adjacent to a CSF infected country or *zone* (for example, bordering areas where infected wild pigs are present).

An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is CSFV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Recognitions for freedom from CSFV infection should, as a consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement standstill orders, etc.).

Article 15.2.25.

Surveillance strategies

1. Introduction

~~There are two basic strategies that can be employed for CSF *surveillance* depending on the purpose of the Member for seeking recognition of freedom from CSF. In countries free of CSF,~~ *S~~s~~urveillance* programmes should be designed to detect the presence ~~introduction~~ of CSFV infection in~~to~~ domestic or wild swine. ~~The optimal strategy to meet this objective is most often targeted *surveillance.*~~

~~The population covered by *surveillance* aimed at detecting *disease* and *infection* should include domestic and wild pig populations within the country or *zone* to be recognised as free from CSFV infection. Such *surveillance* may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted *surveillance.*~~

Although *surveillance* may involve opportunistic testing of samples submitted for other purposes, the optimal strategy to meet this objective is usually targeted *surveillance*, ~~*S~~urveillance* is targeted to aimed at the domestic and wild pig population which presents the highest risk of *infection* (for example, swill fed farms, pigs reared outdoors, specific wild pig sub-populations or farms in proximity to infected wild pigs). ~~Each Member will need to identify its individual risk factors.~~ Targeted *surveillance* may include randomized sampling in selected high risk populations, based on the risk factors present. These may include: temporal and spatial distribution of past *outbreaks*, pig movements and demographics, etc.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent *infections* and difficulties associated with differential diagnosis of other *diseases*, serology is often the most effective and efficient *surveillance* methodology. In some circumstances, which will be discussed later, clinical and virological *surveillance* may also have value.

The *surveillance* strategy chosen ~~The Member~~ should be justif~~y~~ied ~~the *surveillance* strategy chosen~~ as adequate to detect the presence of CSFV infection in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of passive *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy. ~~If a Member wishes to apply for recognition by other Members of a specific *zone* within the country as being free from CSFV infection, the design of the~~

~~*surveillance* strategy and the basis for any sampling process would need to be aimed at the population within the *zone*.~~

When applying randomized sampling, either at the level of the entire population or within targeted sub-populations ~~For random surveys,~~ the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalences for the selected populations. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. ~~The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey.~~ The choice of design prevalence and confidence level ~~The Member~~ should be justif~~y~~ied ~~the choice of design prevalence and confidence level~~ based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular, ~~clearly~~ needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the ~~survey design~~ approach selected, the sensitivity and specificity of the diagnostic tests in the target populations ~~employed~~ should be considered ~~are factors~~ in the design, sample size determination and interpretation of the results obtained. ~~Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of *animals* in the target population.~~

Irrespective of the testing system employed, the *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV infection. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as *animals* which may be epidemiologically linked.

2. Clinical ~~and virological~~ surveillance

~~Beyond their role in targeted *surveillance*, clinical and virological *surveillance* for CSF has two aims: a) to shorten the period between introduction of CSF virus into a *disease* free country or *zone* and its detection, and b) to confirm that no unnoticed *outbreaks* have occurred.~~

~~In the past,~~ The value of clinical ~~identification of *cases* was the cornerstone of early detection of CSF. However, emergence of~~ surveillance alone is limited due to the low virulence of some strains of CSF, as well as the emergence of new *diseases* ~~-~~(such as post-weaning multisystemic wasting syndrome, and porcine dermatitis and nephropathy syndrome ~~– have made such reliance less effective, and, in countries where such *diseases* are common, can add significant risk of masking the presence of CSF~~) which can mask the presence of CSF. Therefore, clinical surveillance should be supplemented, as appropriate, by serological and virological surveillance.

~~The spectrum of *disease* signs and gross pathology seen in CSF infections, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a *surveillance* tool. These factors, along with the compounding effects of concurrent *infections* and *diseases* caused by ruminant pestiviruses, dictate the need for *laboratory* testing in order to clarify the status of CSF suspects detected by clinical monitoring.~~

~~Nevertheless, c~~Clinical and pathological signs ~~presentation should not be ignored as a tool~~ are useful for early detection; in particular, any cases where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV infections involving low virulence strains, high mortality may only be seen in young *animals*, and adult animals may not show clinical sign. ~~Otherwise close physical examination of susceptible *animals* is useful as a selection criteria for CSF *surveillance*, particularly in diagnostic *laboratories* or *slaughter* establishments or when applied to high risk populations such as swill feeding operations.~~

~~The difficulties in detecting chronic *disease* manifested by non-specific clinical signs and delayed seroconversion and seronegativity, in persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a *herd* investigation, such *animals* are likely to be in a~~

~~minority and would not confound a diagnosis based on serology. Individually or as part of recently mixed batches, such *animals* may, however, escape detection by this method. A holistic approach to investigation, taking note of *herd* history, pig, personnel and *vehicle* movements and disease status in neighbouring *zones* or countries, can also assist in targeting *surveillance* in order to increase efficiency and enhance the likelihood of early detection.~~

~~The labour-intensive nature of clinical, pathological and virological investigations, along with the smaller 'window of opportunity' inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological screening as the best method for *surveillance*. However, *surveillance* based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. *Herds* predominated by adult *animals*, such as nucleus *herds* and artificial insemination studs, are particularly useful groups to monitor, since *infection* by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.~~

~~Clinical and virological monitoring may also provide a high level of confidence of rapid detection of *disease* if a sufficiently large number of clinically susceptible *animals* is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large-scale screening for the presence of virus, at reasonable cost.~~

Wild pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any *surveillance* scheme and should, ideally, be monitored for virus as well as antibody.

3. Virological surveillance

Virological *surveillance* should be conducted using tests described in the *Terrestrial Manual*:

a) to monitor at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to test abnormal daily mortality, to ensure early detection of *infection*.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. Epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in disease free areas.

~~Vaccine design and diagnostic methodologies, and in particular methods of virus detection, are increasingly reliant on up to date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing *disease*. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in *disease* free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE Reference Laboratory for genetic and antigenic characterisation.~~

~~3~~4. Serological surveillance

Serological *surveillance* aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

a. natural *infection* with CSFV;

b. ~~legal or illegal~~ vaccination against CSF;

c. maternal antibodies ~~derived from an immune sow (maternal antibodies) are usually found only up to 4.5 months of age, but, in some individuals, maternal antibodies can be detected for considerably longer periods~~;

d. cross-reactions with other pestiviruses;

e. non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a *surveillance* strategy based on serology. Antibodies to bovine viral diarrhoea virus (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity~~. Although persistently infected immunotolerant pigs are themselves seronegative, they continuously shed virus, so the prevalence of antibodies at the *herd* level will be high.~~

CSFV may lead to persistently infected, sero-negative young *animals*, which continuously shed virus. CSFV infection may also lead to c~~C~~hronically infected pigs which may have undetectable or fluctuating antibody levels. Even though serological methods will not detect these *animals*, such *animals* are likely to be in a minority and would not confound a diagnosis based on serology as part of a *herd* investigation.

It may be possible to use sera collected for other survey purposes for CSF *surveillance*. However, the principles of survey design described in this chapter and the requirement for statistical validity should not be compromised.

~~The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of *infection* by field strains or other pestiviruses. Because clustering may signal field strain *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive *animals* is always epidemiologically significant and therefore should be investigated.~~

~~In countries or *zones* that are moving towards freedom, serosurveillance can provide valuable information on the disease status and efficacy of any control programme.~~ In countries, *zones* or *compartments* that are heading towards freedom from CSF and have recently discontinued the use of vaccination, ~~T~~targeted serosurveillance of young, unvaccinated *animals* ~~stock will indicate whether newly~~ can provide useful information on possible virus circulation ~~circulating virus is present, although the presence of maternal antibody will also need to be considered~~. Maternal antibodies are usually found up to four and a half months of age and can interfere with the interpretation of serological results. ~~If conventional attenuated vaccine is currently being used or has been used in the recent past, serology aimed at detecting the presence of field virus will likewise need to be targeted at unvaccinated *animals* and after the disappearance of maternal antibody. General usage in such situations may also be used to assess levels of vaccine coverage.~~

Marker v~~V~~accines ~~also exist which~~, when used in conjunction with accompanying DIVA tests as described in the *Terrestrial Manual* ~~dedicated serological tests~~, may allow discrimination between vaccinal antibody and that induced by ~~field~~ natural *infection*. ~~Such tools, described in the *Terrestrial Manual*, will need to be fully validated. They do not confer the same degree of protection as that provided by conventional vaccines, particularly with respect to preventing transplacental *infections*. Furthermore,~~ However, the interpretation of serosurveillance results using DIVA techniques is only meaningful on a *herd* level ~~such differentiation requires cautious interpretation on a *herd* basis~~.

~~The results of random or targeted serological surveys are important in providing reliable evidence that no CSFV infection is present in a country or *zone*. It is therefore essential that the survey be thoroughly documented.~~

~~The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing freedom, has occurred. Such changes include but are not limited to:~~

~~f. an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;~~

~~g. an increase in the volume of imports or a change in their country or *zone* of origin;~~

~~h. an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or *zones*;~~

~~i. an increased entry from, or exposure to, infected wild pig populations of adjacent countries or *zones*.~~

Article 15.2.26.

Countries, zones or compartments declaring freedom from CSF: additional surveillance procedures

1. Country or zone free of CSF

In addition to the general conditions described above, a Member seeking recognition of CSF freedom for the country or a *zone*~~, whether or not vaccination had been practised,~~ should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and will be planned and implemented according to the general conditions and methods described in this chapter.~~,~~ The objective is to demonstrate the absence of CSFV infection in domestic pigs and ascertain the infection status in wild pig populations, as described in Article 15.2.28. This requires the support of a national or other *laboratory* able to undertake identification of CSFV infection through virus detection and serological tests described in the *Terrestrial Manual*.

2. Compartment free of CSF

The objective of *surveillance* is to demonstrate the absence of CSFV infection in the *compartment*. The provisions of Chapters 4.3. and 4.4. should be followed. The frequency and intensity of *surveillance* should be defined and adapted to the prevailing epidemiological situation in the country or *zone*. Any deterioration in the epidemiological situation should trigger a review of the biosecurity measures and an intensification of *surveillance*. The effective separation of the ~~two~~ subpopulations should be demonstrated. To this end, a *biosecurity plan* that includes but is not limited to the following provisions should be implemented:

a. proper containment of domestic pigs;

b. control of movement of *vehicles* with cleaning and *disinfection* as appropriate;

c. control of personnel entering into the *establishments* and awareness of risk of fomite spread;

d. prohibition of introduction to the *establishments* of wild caught *animals* and their products;

e. record of animal movements into and out of *establishments*;

f. information and training programmes for farmers, processors, *veterinarians*, etc.

The *biosecurity plan* implemented also requires internal and external monitoring by the *Veterinary Authority*. This monitoring should include:

g. periodic clinical and serological monitoring of *herds* in the country or *zone*, and adjacent wild pig populations following these recommendations;

h. *herd* registration;

i. official accreditation of *biosecurity plans*;

j. periodic monitoring and review.

Monitoring the CSF status of wild and domestic pig populations outside the *compartment* will be of value in assessing the degree of risk they pose to the CSF free *compartment*. The design of a monitoring system should follow the provision described in this Chapter and in Chapter 1.4. ~~is dependent on several factors such as~~

~~the size and distribution of the population, the organisation of the *Veterinary Services* and resources available. The occurrence of CSF in wild and domestic pigs may vary considerably among countries. *Surveillance* design should be epidemiologically based, and the Member should justify its choice of design prevalence and level of confidence based on Chapter 1.4.~~

~~The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include government wildlife authorities, wildlife conservation organisations, hunter associations and other available sources. The objective of a *surveillance* programme when the *disease* is already known to exist should be to determine the geographic distribution and the extent of the *infection*.~~

Article 15.2.27.

Recovery of free status: additional surveillance procedures

In addition to the general conditions described in ~~the above-mentioned articles~~ this chapter, a Member seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active *surveillance* programme to demonstrate absence of CSFV infection.

Populations under this *surveillance* programme should include:

a. *establishments* in the proximity of the *outbreak*;

b. *establishments* epidemiologically linked to the *outbreak*;

c. *animals* used to re-populate affected *establishments* and any *establishments* where contiguous culling is carried out;

d. wild pig populations in the area of the *outbreak*.

In all circumstances, a Member seeking reestablishment of country or *zone* freedom from CSF ~~with vaccination or without vaccination~~ should report the results of an active and a passive *surveillance* programme. ~~in which t~~The pig population should undergo~~es~~ regular clinical, pathological, virological, and/or serological examination, planned and implemented according to the general conditions and methods described in these recommendations. ~~The *surveillance* should be based on a statistically representative sample of the populations at risk.~~ To regain CSF free status, the *surveillance* approach should provide at least the same level of confidence as demonstrated during the previous declaration of freedom.

Article 15.2.28.

Surveillance for CSFV infection in wild pigs

1. The objective of a *surveillance* programme is to determine the CSFV infection status of wild pigs, as well as the geographic distribution and prevalence, if present. While the same principles apply, *surveillance* in wild pigs presents challenges beyond those encountered in domestic populations in each of the following areas:
   a) determination of the distribution, size and movement patterns associated with the wild pig population;
   b) assessment of the possible presence of CSF within the population;
   c) determination of the practicability of establishing a *zone*.

~~2.~~ ~~The design of a monitoring system for wild pigs is dependent on several factors such as the organisation of the *Veterinary Services* and resources available.~~ The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information to aid in the design of a monitoring system may include wildlife conservation organisations, hunter associations ~~and other available sources~~, etc. ~~The objective of a *surveillance* programme is to determine if a given *disease* is present, and if so, at what prevalence.~~

~~3~~2. Estimates of wild pig populations can be made using ~~advanced~~ a variety of methods ~~(e.g.~~ including radio tracking, linear transect method, capture/recapture~~)~~ or estimates based on the number of *animals* hunted ~~traditional methods based on the number of *animals* that can be hunted to allow for natural restocking (hunting bags)~~.

~~4~~3. For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which wild pigs range in order to delineate the *epidemiological units* within the monitoring programme. It is often difficult to define *epidemiological units* for wild *animals*. The most practical approach is based on natural and artificial barriers.

~~5~~4. The monitoring programme should also include *animals* found dead, road kills, *animals* showing abnormal behaviour or exhibiting gross lesions during dressing.

~~6~~5. There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:

a. areas with past history of CSF;

b. sub-regions with large populations of wild pigs;

c. border regions with CSF affected countries or *zones*;

d. interface between wild and domestic pig populations;

~~e. picnic and camping areas;~~

~~f~~e. farms with free-ranging pigs;

~~g. garbage dumps;~~

~~h~~f. other risk areas determined by the *Veterinary Authority* such as garbage dumps and picnic and camping areas.

- - - - - - - - - - - - - -

— text deleted

Annex XXIX

CHAPTER ~~8~~15.~~16~~4.

SWINE VESICULAR DISEASE

EU comment

The EU thanks the OIE TAHSC for its work and supports the proposed changes, but cannot support the chapter if some other changes are not included.

In particular, the chapter needs the inclusion of an article on conditions for importation of fresh meat from an infected country or zone after article 15.4.8. This is, in view of the low impact of the disease, which was even proposed for delisting during the last meeting of the ad hoc group on disease listing. Due to the pathogenesis of SVD (short viremic period, no replication of virus in the muscles), the risk of virus being present in muscle meat is considered to be negligible. Nevertheless, some risk mitigation measures are proposed.

The EU proposals are included in the text below.

Article ~~8~~15.~~16~~4.1.

The pig is the only natural host for swine vesicular disease (SVD) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild.

EU comment

For consistency, in particular with other chapters concerning pig disease, such as the CSF chapter, since there are new definitions for wildlife and the role of wild pigs in SVD epidemiology have never been substantiated, a new sentence should be added after the sentence above:

"For the purposes of this chapter, a distinction is made between domestic pig and captive wild pig populations on the one hand, and wild pigs and feral pig populations on the other hand."

~~For the purposes of the *Terrestrial Code*, the *incubation period* for swine vesicular disease (SVD) shall be 28 days.~~

For the purposes of ~~this Chapter,~~ the *Terrestrial Code*, SVD is defined as an infection of ~~susceptible animals include~~ domestic ~~and wild~~ pigs.

EU comment

For the same reason as above, the words "domestic pigs" should be replaced by "domestic and captive wild pigs".

Domestic pig is defined as all domesticated pigs, permanently captive or farmed free range, used for the production of *meat* for consumption, for the production of other commercial products or for breeding these categories of pigs.

For the purposes of the *Terrestrial Code*, the *incubation period* for SVD shall be 28 days.

~~For the purposes of this Chapter, a case includes an animal infected with SVD virus (SVDV).~~

~~For the purposes of *international trade*,~~ ~~t~~This chapter deals not only with the occurrence of clinical signs caused by SVD~~V~~ virus (SVDV), but also with the presence of infection with SVDV in the absence of clinical signs.~~For the~~

~~purposes of this Chapter, virus~~ The following defines the occurrence of infection ~~means presence of~~ with SVDV ~~as demonstrated by~~:

1. virus isolation, or detection of virus antigen or virus nucleic acid, or
2. seroconversion, or
3. clinical signs associated with serological evidence, or
4. clinical signs or serological evidence associated with an epidemiological link.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

A Member should not impose trade bans in response to a notification of *infection* with SVDV in wild pigs according to Article 1.2.3. of the *Terrestrial Code*.

Article 15.4.1. bis.

Determination of the SVD status of a country, zone or compartment

The SVD status of a country, *zone* or *compartment* can only be determined after considering the following criteria, as applicable:

1. SVD should be notifiable in the whole territory, and all clinical signs suggestive of SVD should be subjected to appropriate field and/or *laboratory* investigations;
2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of SVD;
3. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment*;
4. the *Veterinary Authority* should have current knowledge about the population and habitat of wild pigs in the country or *zone*;

EU comment

As the role of wild pigs in the epidemiology of SVD has never been substantiated, this point 4 should be deleted.

5. for domestic pigs, appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Articles 15.4.14. to 15.4.19.

Article ~~8~~15.~~16~~4.2.

SVD free country, *zone* or *compartment*

~~Susceptible animals in the SVD free country or *zone* or *compartment* should be separated from neighbouring infected countries or *zones* by animal health measures (bio-security measures, which may include a *buffer zone*) that effectively prevent the entry of the virus, or by physical barriers.~~

~~The SVD status of a country, *zone* or *compartment* can only be determined by applying *surveillance* recommendations described Chapter 1.4. according to two possibilities:~~

1. Historically free status

   A country or *zone* may be considered free from the *disease* without formally applying a pathogen specific *surveillance* programme if the provisions of Article 1.4.6. are complied with.

2. Free status as a result of a specific surveillance programme

A country, *zone* or *compartment* which does not meet the conditions of point 1 above may be considered free from SVD when:

a) *surveillance* for both SVD and SVDV infection in accordance with Articles15.4.14 -15.4.19 and Chapter 1.4. has been in place for at least 3 years;

b) no *outbreak* of SVD and no evidence of SVDV circulation has been found during the past 3 years;

c) regulatory measures for the prevention and control of SVD have been implemented, including the control of the movement of ~~susceptible animals~~ pigs and other relevant measures for preventing the entry of the virus.

EU comment

For the same reason as in article 15.4.1, the words "domestic pigs" should be replaced by "domestic and captive wild pigs".

~~If a *stamping out policy* was applied in respect of the most recent *outbreak*, the requirement of 3 years in points a) and b) above is shortened to 12 months.~~

Article ~~8~~15.~~16~~4.3.

SVD infected country or zone

A~~n~~ SVD infected country or *zone* is ~~a country or *zone*~~ one that does not fulfill the requirements to be considered as free.

EU comment

For consistency with other chapters, the above sentence should begin with "For the purpose of this chapter".

Article ~~8~~15.~~16~~4.4.

Establishment of a containment zone within a~~n~~ SVD free country or SVD free zone

In the event of ~~a~~ limited *outbreak*~~s~~ within a~~n~~ SVD free country or SVD free *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*. For this to be achieved, the *Veterinary Authority* should be able to provide documented evidence that:

1. the *outbreak* is limited based on the following factors:

a) immediately on suspicion, a rapid response including notification has been made;

b) standstill of ~~animal~~ pig movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;

EU comment

For the same reason as in article 15.4.1, the words "pig" above should be replaced by "domestic and captive wild pigs".

c) the *infection* has been confirmed;

~~c~~d) epidemiological investigation (trace-back, trace-forward) has been carried out~~completed~~;

~~d~~c) the primary outbreak has been identified and investigations of the likely ~~the~~ source of the *outbreak* has~~ve~~ been ~~identified~~ carried out;

~~e~~f) all *cases* have been shown to be epidemiologically linked;

2. *surveillance* in accordance with Articles15.4.14 -15.4.19 and Chapter 1.4. is in place and demonstrates that there are no undetected *cases* in the *containment zone*;

3. a *stamping-out policy* has been applied;

4. the pig population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*;

~~4~~5. increased passive and targeted *surveillance* in accordance with Articles15.4.14 -15.4.19 and Chapter 1.4. in the rest of the country or *zone* has been carried out and has not detected any evidence of *infection*;

~~5~~6. measures to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, are in place.

The free status of the area outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The suspension of free status of this area could be lifted irrespective of the provisions of Article ~~8~~15.~~16~~4.5., once the *containment zone* is clearly established, by complying with points 1 to ~~5~~6 above.

The recovery of the SVD free status of the *containment zone* should follow the provisions of Article ~~8~~15.~~16~~4.5.

When importing from *containment zones*, provisions of Articles ~~8~~15.~~16~~4.6., ~~8~~15.~~16~~4.9~~8~~., ~~8~~15.~~16~~4.1~~0~~., 15. 4.12. and ~~8~~15.~~16~~4.13., concerning the importation from countries or *zones* considered infected with SVD, should be applied.

Article ~~8~~15.~~16~~4.5.

Recovery of free status

When a~~n~~ SVD *outbreak* ~~or SVDV infection~~ occurs in a~~n~~ SVD free country or *zone*, one of the following waiting periods is required to regain the status of SVD free country or *zone*:

1. 2 months after the *stamping-out* of the last *case*, where a *containment zone* and serological *surveillance* have been applied in accordance with this chapter and Chapter 1.4.; or

2. 12 months after the *stamping-out* of the last *case*, where the conditions for the establishment of a *containment zone* are not fulfilled, a *stamping-out policy* and serological *surveillance* have been applied in accordance with this chapter and Chapter 1.4.

Where both a *stamping-out policy* and serological *surveillance* in accordance with this chapter ~~X.X.~~ have not been practiced, the above waiting periods do not apply, and Article ~~8~~15.~~16~~4.2. applies.

Article ~~8~~15.~~16~~4.6.

Direct ~~T~~transfer of pigs from an infected zone for ~~directly to~~ slaughter ~~of SVD susceptible animals from an infected zone to~~ in a free zone~~ within a country~~

In order not to jeopardise the status of a free *zone*, pigs ~~SVD susceptible animals~~ should only leave ~~the~~ an *infected zone* if ~~moved by mechanised~~ transported directly to *slaughter* in ~~to~~ the nearest designated *abattoir*~~, located in the *buffer zone* (if established), directly to *slaughter*~~ under the following conditions:

~~In the absence of an *abattoir* in the *buffer zone*, or in the absence of a *buffer zone*, live SVD susceptible animals can be transported to the nearest *abattoir* in a free *zone* directly to *slaughter* only under the following conditions:~~

1. no ~~SVD susceptible animal~~ pig has been introduced into the *establishment* of origin and no ~~animal~~ pig in the *establishment* of origin has shown clinical signs of SVD for at least 60 days prior to movement;

2. a representative sample of ~~animals of~~ pigs in the *herd* of origin, including all ~~animals~~ pigs to be moved for *slaughter* has been serologically tested with negative findings;

3. the ~~animals~~ pigs were kept in the *establishment* of origin for at least 2 months prior to movement;

4. SVD has not occurred within a 1 kilometre radius of the *establishment* of origin for at least 2 months prior to movement;

5. the ~~animals~~ pigs ~~must~~ should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other ~~susceptible animals~~ pigs;

6. such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of ~~animals~~ pigs from the *infected zone* and, to be re-approved, ~~must~~ should apply *disinfections* ~~able to~~ that will destroy ~~any~~ residual infectivity;

7. *vehicles* and the *abattoir* ~~must~~ should be subjected to thorough cleansing and *disinfection* ~~able to~~ that will destroy ~~any~~ residual *infectivity* immediately after use.

All products obtained from the ~~animals~~ pigs and any products coming into contact with them ~~must~~ should be identified and traded only on domestic market.

~~Animals~~ Pigs moved into a free *zone* for other purposes ~~must~~ should be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article ~~8~~15.~~16~~4.9~~8~~.

Article ~~8~~15.~~16~~4.7

Recommendations for importation from SVD free countries, zones or compartment

for domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the ~~animals~~ pigs:

1. showed no clinical sign of SVD on the day of shipment;
2. were kept in a~~n~~ SVD free country, *zone* or *compartment* since birth or for at least the past 60 days.

~~Article 8.16.8.~~

~~**Recommendations for importation from SVD free countries or zones**~~

~~for wild pigs~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals pigs:~~

~~1. showed no clinical sign of SVD on the day of shipment;~~

~~2. come from an SVD free country or *zone*;~~

~~if the country or *zone* of origin has a common border with a country or *zone* considered infected with SVD:~~

~~3. were kept in a *quarantine station* for the 60 days prior to shipment and were subjected to a prescribed serological test for SVD with negative results during that period.~~

Article ~~8~~15.~~16~~4.9~~8~~.

Recommendations for importation from countries or zones considered infected with SVD

for ~~domestic and wild~~ pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the ~~animals~~ pigs:

1. showed no clinical sign of SVD on the day of shipment;

2. were kept in a *quarantine station* for the 60 days prior to shipment and were subjected to a prescribed serological test for SVD with negative findings at the end of ~~during~~ that period.

EU comment

The conditions in the point 2 above are far too restrictive, for a disease that does not represent the same risk and contagiousness as others such as FMD or CSF.

The EU thus proposes to replace the words "a quarantine station" by the words "in isolation" and to add after the words "prior to shipment" the words: "in an *establishment* where no *case* of SVD was reported during that period, and not situated within one km from an *outbreak* occurring in the last 60 days,". As used in other chapters too, the word isolation could be defined in the Glossary.

Article ~~8~~15.~~16~~4.~~10~~9.

Recommendations for importation from SVD free countries or zones or compartments

for semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

   a) showed no clinical sign of SVD on the day of collection of the semen;

   b) were kept in a~~n~~ SVD free country or *zone* or *compartment* for not less than 60 days prior to collection;

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.6.

Article ~~8~~15.~~16~~4.11~~0~~.

Recommendations for importation from countries or zones considered infected with SVD

for semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificat*e attesting that:

1. the donor ~~animals~~ pigs showed no clinical sign of SVD on the day of collection of the semen and were subjected to a prescribed serological test for SVD with negative findings;

2. the donor ~~animals~~ pigs were kept in the *exporting country* or *zone* for the 60 days prior to collection, in an *establishment* or *artificial* insemination *centre* where no *case* of SVD was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated within one km from an *outbreak* occurring in the last 60 days;

3. a representative sample of ~~animals~~ pigs ~~of~~ in the *herd* of origin has been serologically tested with negative findings;

4. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.6.

Article ~~8~~15.~~16~~4.1~~2~~1.

Recommendations for importation from SVD free countries, zones or compartments

for *fresh meat* of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals:

1. which have been kept in a~~n~~ SVD free country, *zone* or *compartment* since birth or for at least the past 60 days;

2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for SVD with favourable outcome.

All the necessary measures have been taken to avoid cross contamination.

EU comment

The conditions in the article 15.4.11 should also apply to meat products.

Furthermore, there should be an article for the importation of fresh meat from infected countries or zones, which would read:

Recommendations for importation from SVD infected countries or zones

for *fresh meat* of pigs

***Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *meat* comes from animals:**

1. originating from *establishments* situated in an area of 1 kilometre radius within which SVD has not occurred for at least 2 months prior to slaughter;

2. originating from *establishments* in which no pig has shown clinical signs of SVD for at least 2 months prior to slaughter,

3. originating from *establishments* in which a representative sample of pigs has been serologically tested with negative results, twice at an interval of not less than 28 days and not more than 40 days, the second test not less than 7 days and not more than 28 days before slaughter;

4. that were kept in the *establishment* of origin since birth or for at least 2 months prior to slaughter;

Article 15.4.12.

Recommendations for importation from SVD infected countries, zones or compartments

for *meat products* of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* products have been processed in an establishment approved by the *Veterinary Authority* so as to ensure the destruction of the SVD virus by either:

1. Heat treatment in a hermetically sealed container with an F0 value of 3,00 or more, or

2. heat treatment at a minimum temperature of 70 °C, which must be reached throughout the meat, or

3. heat treatment in a hermetically sealed container to at least 60 °C for a minimum of 4 hours, during which time the core temperature must be at least 70 °C for 30 minutes, or

EU comment

The treatments 2 and 3 above are not clear and not consistent. What should be clearly stated is the time/temperature couple to be applied throughout the product. Moreover, a point 6 should be added for provisions for any other treatment of proven equivalent efficacy.

4. natural fermentation and maturation of not less than nine months, resulting in the following characteristics: Aw value of not more than 0,93 or a pH value of not more than 6,0 , and

5. all the necessary measures have been taken to avoid cross contamination.

Article 8~~15~~.16~~4~~.13

Recommendations for the importation of *meat products* of pigs ~~(either domestic or wild)~~, or for products of ~~animal~~pig origin (from *fresh meat* of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use~~, or for trophies derived from wild pigs~~

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products~~:~~

~~1.~~ have been prepared:

~~a~~1. ~~exclusively~~ from *fresh meat* meeting the conditions laid down in Article 8~~15~~.16~~4~~.12~~1~~, ~~as relevant~~; or

2. from *meat products* meeting the conditions laid down in Article 15.4.12.;

~~b~~) ~~in a processing establishment:~~

~~i) approved by the *Veterinary Authority* for export purposes;~~

~~ii) processing only *meat* meeting the conditions laid down in Article 8.16.12, as relevant;~~

~~OR~~

~~2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the SVD virus.~~

Article 15.4.14.

EU comment

These new articles on surveillance are important and quite substantial. The EU needs time to study them and would propose some comments to the OIE in the next months.

Surveillance: introduction

The Articles 1i.4.14. – 15.4.19. define the principles and provides a guide for the *surveillance* of SVD complementary to Chapter 1.4., applicable to Members seeking to determine their SVD status for the whole country or a *zone*, or a *compartment*. Guidance on *surveillance* for countries seeking re-establishment of freedom from SVD for the whole country or a *zone*, or a *compartment* following an *outbreak*, as well as for demonstrating the maintenance of SVD free status is also provided.

Consideration should be given to the known characteristics of SVD epidemiology, which include the impact of different production systems on *disease* spread, the lack of pathognomonic gross lesions and clinical signs, and the frequency of clinically inapparent *infection*. Serological cross-reactivity with other agents has to be taken into consideration when interpreting data from serological surveys.

Clinically, SVD may be indistinguishable from foot and mouth disease (FMD) and this is its main importance. And since any vesicular condition in pigs may be FMD, it is therefore essential that *cases* of SVD be distinguished urgently from FMD by laboratory investigation.

Article 15.4.15.

Surveillance: general conditions and methods

1. A surveillance system in accordance with Chapter 1.4. should be under the control of the *Veterinary Authority*.

   a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* or SVDV infection should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of SVD to a *laboratory* for SVD diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2. The SVD *surveillance* programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspect case of SVD. All suspected cases of SVD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to an approved *laboratory*. This requires that sampling kits and other equipment are available for those responsible for the *surveillance*. Personnel responsible for the *surveillance* should be able to call for assistance from a team with expertise in vesicular diseases diagnosis and control;

   b) implement when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of *animals* (*risks* linked to the types of production cycle, local trade pattern, holding with poor bio-security measures, possible direct or indirect contact with other pigs).

   An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is SVD. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Recognition for freedom from SVD infection should, as a consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the *animals* concerned were submitted during the investigation (quarantine, movement stand-still orders, etc.).

Article 15.4.16.

Surveillance strategies

1. Introduction

   The population targeted by *surveillance* programs aimed at identifying *disease* and *infection* should include domestic pig populations within the country or *zone* or *compartment* to be recognised as free from SVD.

Given the existence of clinically inapparent *infection* and difficulties associated with clinical diagnosis of SVD, serology is often the most effective and efficient *surveillance* methodology. In some circumstances, which will be discussed later, clinical and virological *surveillance* may also have a value.

2. Clinical surveillance

SVD can be sub-clinical, mild or severe depending on the strain of virus involved, the route and dose of infection, and the husbandry condition under which the pigs are kept.

Clinically, SVD is indistinguishable from FMD and, when a vesicular condition is seen in pigs, it must be assumed to be FMD until investigated by *laboratory* tests and proven otherwise.

Nevertheless, SVD caused by mild strains may remain unobserved, and in this case the value of clinical examination alone is insufficient as a *surveillance* tool: in this case serology is often the most effective and efficient *surveillance* methodology.

Clinical *surveillance* and laboratory testing should always be applied in series to clarify the status of suspected cases detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspects, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.

Identification of suspected cases is vital to identify the sources of SVDV. It is essential that SVDV isolates are sent regularly to a Reference Laboratory to enable the determination of the molecular, antigenic and other biological characteristics of the virus.

3. Virological surveillance

Virological *surveillance* using tests described in the *Terrestrial Manual* should be conducted:

a) to monitor an at risk population;

b) to confirm clinically suspected cases;

c) to follow up positive serological results.

The most suitable samples for virological testing are vesicular lesion materials from clinically affected pigs and faeces from pigs without lesions.

4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against SVD. Positive SVD antibody test results can have three possible causes:

a) natural infection with SVD;

b) maternal antibodies derived from immune sows (no published data exist so far on the duration of maternal passive immunity against SVD);

c) non-specific reactors.

Article 15.4.17.

The use and interpretation of serological tests

Any positive test result should be followed up immediately using appropriate clinical, epidemiological, serological and virological investigations of the reactor *animals* at hand, and of susceptible *animals* of the same *epidemiological unit* and those that have been in contact or otherwise epidemiologically associated with the reactor *animals*. If the follow-up investigations provide no evidence for SVDV active infection, the reactor *animal* shall be classified as

non SVD infected. In all the other cases, including the absence of such follow-up investigations, the reactor *animals* should be classified as SVD positive.

It is suggested that in the primary sampling units where at least one *animal* reacts positive to the screening test, the following strategy should be applied (Figure 1):

1. In case of positive results to the screening test (ELISA), all positive sera from the *herd* should be tested using the Virus Neutralization (VN) test. If there are pigs that test serologically positive by VN test, the positive sample may be tested to identify the isotype of antibody (IgM or IgG).

2. The positive *herd* should undergo clinical examination with collection of samples for virological testing (vesicular lesions and/or faeces). In the presence of symptoms compatible with SVD and/or detection of virus, the *herd* is to be considered infected.

3. Identification of the isotype of antibody present in positive sera can be helpful in the evaluation of the epidemiological meaning of results, as sera from recently infected pigs usually contain specific IgM alone, subsequently both IgM and IgG, and later exclusively IgG. Therefore, in the sero-positive *herd*:

    a) The clinical examination and virological testing of sero-positive *animals* and *animals* in contact should be targeted to the IgM positive *animals* and to those living in their proximity, rather than to the IgG positives.

    b) The presence of IgG positives exclusively may indicate a low likelihood of SVDV circulation.

    c) The presence of a single reactor, containing exclusively IgM also on re-testing, without increase of VN titre, in the absence of symptoms and seroconversion in *animals* in contact, is usually due to non-specific reaction.

4. In the case of seroreactor *herds* without clinical signs or positive virological findings, after an adequate interval of time has lapsed (at least 7 days), following clinical examination, a second serum sample should be collected from the positive *animals* and also from a representative number of pigs in contact with the positives in the primary sampling. These samples are tested using ELISA and VN test and antibody titres at the time of retest should be equal to or lesser than those observed in the initial test if virus is not circulating.

EU comment

The word "seroreactor" above is the right one and should also be used in the figure 1 instead of "positive".

5. In case of the detection of an *outbreak*, an epidemiological investigation has to be performed and a representative sample of *animals* in all epidemiologically linked *herds* should be serologically tested.

Possible alternative strategies may be adopted, but in this case the country should justify the procedure chosen as adequate to detect the presence of SVDV infection. Possible shortcomings in the sensitivity of alternative diagnostic strategies should be addressed by appropriate changes in the *surveillance* design and in the sample size.

Fig 1: Should confirm that SVD virus could be demonstrated in samples from pigs on seroreactor *herds* before declaring an *outbreak*, even if clinical signs suggestive of SVD were found.

Article 15.4.18.

Countries, zones or compartments declaring freedom from SVD: Additional surveillance procedures

1. Country or zone free of SVD

    In addition to the general conditions described in this chapter, a Member declaring freedom from SVD for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and the design of the *surveillance* programme will depend on the prevailing epidemiological circumstances. It will be planned and implemented to demonstrate the absence of SVDV infection in susceptible populations, during the preceding 3 years, according to general conditions and methods described in this chapter. This requires the support of a national or other *laboratory* able to undertake identification of SVDV infection through virus detection and antibody tests described in the *Terrestrial Manual.*

This *surveillance* may be targeted to a pig population at specific *risks* linked to the types of production, local trade patterns, holdings with poor bio security measures in place.

2. Compartment free of SVD

The objective of *surveillance* is to demonstrate the absence of SVDV infection in the *compartment*. The provisions of Chapters 4.3. and 4.4. should be followed. The frequency and intensity of *surveillance* should be defined and adapted to the prevailing epidemiological situation in the country or *zone*. Any deterioration in the epidemiological situation should trigger a review of the biosecurity measures and an intensification of *surveillance*.

Article 15.4.19.

Recovery of status: Additional surveillance procedures

In addition to the general conditions described in this chapter, a country, *zone* or *compartment* regaining freedom from SVDV infection should show evidence of an active *surveillance* programme aimed to demonstrate the absence of the *infection*.

The population under this *surveillance* programme should include:

a) in the *establishments* in the area of the *outbreak*;

b) in the *establishments* epidemiologically linked to the *outbreak*;

c) used to re-populate affected *establishments*.

This will require *surveillance* incorporating virus detection and antibody tests described in the *Terrestrial Manual*.

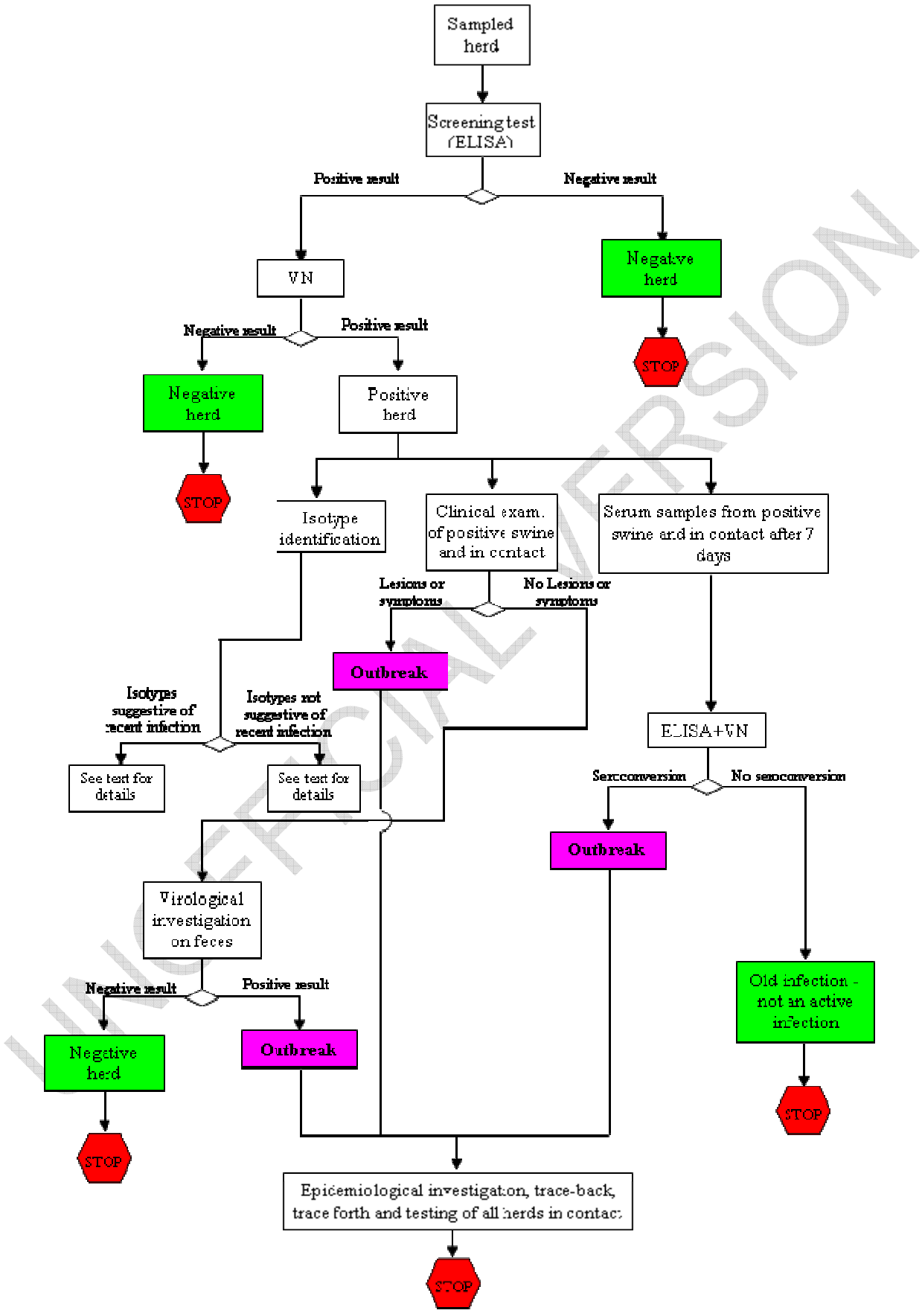
In all circumstances, a Member self-declaring freedom of a country, *zone* or *compartment* after an *outbreak*, should report the results of an active *surveillance* programme in which pigs undergo regular active *surveillance*, planned and implemented according to the general conditions and methods described in this chapter.

EU comment

The word "sero-reactor" in article 15.4.17 point 4 is the right one and should also be used in the figure 1 below instead of "positive".

Moreover, it should be clearer that the three boxes below the box on sero-reactor herds should be implemented, not only one or two.

Figure 1. ***Use and interpretation of serological tests***



Annex XXX

CHAPTER 3.4

COMMUNICATION

EU comment

The EU can support the inclusion of the proposed new chapter, but have some comments included in the text.

Article 3.4.1.

General considerations

In general communication entails the exchange of information between various individual, institutional and public audiences for purposes of informing, guiding and motivating action. The application of the science and technique of communication involves modulating messages according to situations, objectives and target audiences.

The recognition of communication as a discipline of the *Veterinary Services* and its incorporation within it is critical for their operations. The integration of veterinary and communication expertises is essential for effective communication.

Communication should be an integral part of all the activities of the *Veterinary Services* including animal health (surveillance, early detection and rapid response, prevention and control), animal welfare and veterinary public health (food safety, zoonoses) and veterinary medicine.

Objectives of this chapter on communication for the *Veterinary Services* are to provide guidance for the development of a communication system, strategic and operational communication plans and elements to assess their quality.

Article 3.4.2.

Principles of communication

1. *Veterinary Services* should have the authority and capability to communicate on matters within their mandate.

2. Veterinary and communication expertises should be combined.

3. Communication should be targeted and follow the fundamental criteria of transparency, consistency, timeliness, balance, accuracy, honesty and empathy and respect the fundamental principles of quality of *Veterinary Services* (article 3.1.2.).

4. Communication should be a continuous process.

5. *Veterinary Services* should be responsible for planning, implementing, monitoring, evaluating and revising their strategic and operational communication plans.

Article 3.4.3.

Definitions

EU comment

The following sentence should be included: "<u>For the purpose of this chapter, the following definitions apply</u>".

Communication

means the discipline of informing, ~~influencing~~ guiding and motivating individual, institutional and public audiences, ~~preferably~~ ideally on the basis of interactive exchanges, about any issue ~~falling under the mandate of the OIE and~~ under the competence of the *Veterinary Services*.

Crisis

means a ~~time~~ situation of great ~~danger~~ threat, difficulty or uncertainty when ~~problems related to any~~ issues ~~falling~~ under ~~the mandate of the OIE and~~ the competence of the *Veterinary Services* require immediate action.

Crisis Communication

means the process of ~~providing~~ communicating information of potentially incomplete nature within time constraints in the event of a *crisis*. ~~that allows an individual, affected and/or interested parties, an entire community or the general public to make best possible decisions and be informed of and/or accept policy decisions and rationale behind policy decisions during a crisis.~~

EU Comment

The EU recognises the importance of the explanation in the second part of the sentence above; this part should not be deleted.

Outbreak communication

means the process of communicating in the event of an *outbreak*. Outbreak communication includes *notification*.

Article 3.4.4.

Communication system

In addition to the Principles for Communication the following critical elements should be used in conjunction with Chapter 3.1., when planning, implementing and assessing a communication system.

Critical elements

1. Authority and organizational structure

   a) Legislation providing authority to *Veterinary Services* under the responsibility of the CVO to communicate on matters within their mandate

EU comment

The word "CVO" is not defined (point a) above and c) below).

Even when using the definition of the present chapter, the word "communicate" is wide and vague. There should be a description of how and when the "CVO" or the Veterinary Services should/can communicate with respectively other national administrations, Veterinary Services of other countries, international organisations, breeders, general public, etc.

Moreover, the word "legislation" is not relevant in this place and could lead to confusion, thus the words "legislation providing" should be deleted.

   b) Identified and accessible official contact point~~s~~ for communication

EU comment

The point b above is not clear. Is the word "point" singular or plural? Where should be this (these) contact point(s), what should be his (their) link with the "CVO" or Veterinary Services and what should be the relations with other institutions and the general public?

c) Organizational chart indicating direct link to the CVO through chain of command (e.g. dedicated communication unit, communication officer)

2. Human resources

a) Job descriptions of communication personnel identifying roles and responsibilities

b) Sufficient number of qualified personnel with knowledge, skills, attitude and abilities relevant to communication

c) Continuous training and education on communication provided to communication personnel

3. Financial and material resources

a) Clearly identified budget for communication that provides adequate funding

b) Provision and/or access to appropriate material resources in order to carry out roles and responsibilities: suitable premise/accommodation that is adequately equipped with sufficient office and technical equipment, including information technology and access to the Internet

4. Management of the communication system

a) Roles and responsibilities of the communication unit

i) Report to the CVO

ii) Engaged in decision-making process

iii) Responsible for the planning, implementation and evaluation of the strategic and operational plans for communication and relevant standard operating procedures

iv) Function as contact point on communication issues for the *Veterinary Services*

v) Provide guidance and expertise on communication issues to the *Veterinary Services*

vi) Provide and coordinate continuous education on communication for the *Veterinary Services*

b) Strategic plan for communication

A well-designed strategic plan for communication should support the *Veterinary Services* strategic plan and have management support and commitment. The strategic plan for communication should address all high level organization-wide communication objectives. The plan should be a long-term plan.

A strategic plan for communication should be monitored, periodically reviewed and should identify measurable performance objectives and techniques to assess.

The strategic plan for communication should consider the different types of communication: routine communication, risk communication, outbreak communication and crisis communication.

The key outcomes in effectively implementing a strategic plan for communication are increased knowledge and awareness of issues by the public and stakeholders, higher understanding of the role of the Veterinary Services, higher visibility of and improved trust and credibility in the Veterinary

Services. These will enhance understanding and/or acceptance of policy decisions and subsequent change of perception, attitude and/or behaviour.

c) Operational plans for communication

Operational plans for communication should be based on the assessment of specific issues and should identify specific objectives and target audiences such as staff, partners, stakeholders, media and the general public.

Each operational plan for communication should consist of a well-planned series of activities using different techniques, tools, messages and channels to achieve intended objectives and utilizing available resources within a specific timeframe.

Guidance from the Animal Welfare Working Group to *ad hoc* groups on the development of animal welfare standards

EU comments

The EU welcomes the work carried out by the OIE Working Group on Animal Welfare to provide the *ad hoc* groups with guidance on the development of animal welfare standards.

When 'welfare codes' were first developed in the 1970s and 1980s, they tended to contain truisms such as 'Animals should have adequate space' and 'Noise levels should not be excessive'. Although such statements can be useful to identify important variables in the course of providing more specific advice, they do not provide any implementable information or any means of determining whether a given practice or facility is in compliance. In contrast, an OIE animal welfare standard should contain recommendations that can be implemented, and criteria that can be used to tell whether a given practice or facility is in compliance with the standard.

Outcome-based or animal-based criteria should be used where possible because they are generally related most directly to animal welfare, and because they can be applied to a wide range of production systems. Such criteria can be qualitative (all animals should be able to lie down at the same time without lying on top of each other) or quantitative (no more than 1% of animals should be dead on arrival).

In some cases, input-based or resource-based criteria may be possible, for example if welfare is likely to be reduced by a certain factor in a wide range of systems. Again these can be qualitative (no animal should be hoisted while conscious) or quantitative (ammonia level in the air should not exceed 25 ppm).

In other cases, 'conditional' criteria can be used. These generally specify what actions should be taken under certain conditions. These can include both qualitative and quantitative elements, as in: (1) If more than 2% of birds arrive at the slaughter plant with broken wings, catching crews should be re-trained to catch birds in ways that are less likely to cause injuries. (2) In months where hot weather is expected, stocking density should be reduced so that birds have enough space to perform wing-stretching unimpeded.

For certain variables, it is possible to identify 'critical levels' beyond which welfare is expected to be affected. Such levels are normally determined by scientific research. For example, welfare in many species is noticeably affected if ammonia levels in the air exceed 25 ppm.

For other variables (percent lame, percent dead during transport) there are no critical levels but it may be possible to set or recommend 'performance targets'. In the case of performance targets, an *ad hoc* committee may be able to agree that a certain level of performance should be achieved broadly, for example, that no more than 1% of animals should fall while being moved in a slaughter facility. In other cases, there may be so much variation between breeds or locations that a standard merely identifies variables that should be used to assess performance, and calls for national or breed-specific targets to be set. In such cases it is helpful to provide examples of performance targets from other standards that are broadly applicable under different conditions.

June 25, 2010

DRAFT CHAPTER X.X.X.

ANIMAL WELFARE AND BROILER CHICKEN PRODUCTION

EU comments

The EU notes the improvements of the Draft Chapter on Animal Welfare and Broiler Chicken Production as revised by the *ad hoc* Group and would like to present early general considerations in view of the further development of the chapter.

Only in some cases are comments made on the details of the text, given its draft nature.

The chapter is still in need of some clarifications. There should be a clear distinction between the different headings so that all definitions are listed under definitions etc. One example is the definition of broiler which, as it stands now, also partly defines the scope. Another example is the point on "*Environment and management*". It might be more clear to divide the chapter to make a distinction on what is related to the buildings and to the management etc. Moreover, the list of definitions plays an important role and the EU wishes the OIE to reconsider which definitions should be included or excluded. Repetitions in the text should be avoided when possible.

Article X.X.3. on commercial broiler production systems mostly contain descriptions which may make it more suitable as part of the definitions.

EU also sees that it is very important to ensure a clear scope.

EU recognizes the difficulties in assigning numeric values to measurable given the variations of production systems used by 177 OIE members. Nevertheless, the EU encourages the OIE to develop tables and to keep the figures already in the previous draft. This should especially be the case when there is scientific support for numeric values independent of production system. These might include maximum ammonia-level, light, stocking density, type of flooring etc.

Specific comments are presented within the text.

Article X.X.1.

Definitions

For the purpose of this chapter:

Broiler

means birds of the species *Gallus gallus* kept primarily for commercial meat production.

~~***Cage housing system***~~

~~In a cage housing system the caretaker accesses the birds from outside the enclosure in which the birds~~ they ~~are kept.~~

~~Deep litter housing system~~

In a deep litter housing system the birds are kept on floors that are is covered with bedding material.

Harvesting

means the catching and loading of birds on farm for transportation to the *slaughterhouse.*

Slatted floor ~~housing system~~

~~In a slatted floor~~ means a housing system where the ~~birds~~ broilers are kept on raised floors, on which droppings do n~~'~~ot accumulate**,** but fall through.

~~Litter~~

~~Is a layer of absorbent material covering the floor of the poultry house.~~

~~Poultry house~~

is a covered facility designed to house commercial birds.

Article X.X. 2.

Scope

These recommendations cover the production period from arrival of the chicks on the farm to harvesting the broilers in commercial production systems. These systems include broilers kept in cages, on slatted floors, litter or dirt and indoors or outdoors. Backyard flocks are not included even if the ~~animals~~ broilers or products are traded locally.

This chapter should be read in conjunction with Chapters 7.2., 7.3. and 7.4. on the welfare of the broiler during *transport* to the ~~abattoir~~ *slaughterhouse*.

~~Note 2: Recommendations on the management of the breeding flock and hatchery and for the period between hatching and arrival on the farm to be developed.~~

Article X.X.3.

Commercial broiler production systems

Commercial broiler production systems include:

1. Intensive systems

   ~~Birds~~ Broilers are completely confined in a ~~roofed structure~~ poultry house, with or without environmental control and usually at a higher *stocking density* than in other production systems. ~~Birds~~ Broilers may be kept in cages**,** ~~with (e.g. wire or plastic floor or deep litter floor) or~~ on ~~deep~~ litter~~,~~ or slatted floors or a combination**.**

2. Semi intensive systems

   ~~Birds~~ Broilers are confined in a ~~roofed structure~~ poultry house but provided with ~~an~~ access to a restricted outdoor area. ~~They may be kept in cages (e.g. wire or plastic floor or deep litter floor) or on deep litter, a slatted floor or a combination of the two.~~

3. Extensive systems

   ~~Birds~~ Broilers are not confined throughout their production period in a ~~roofed structure~~ poultry house and are usually kept at a lower *stocking density* than in intensive or semi intensive systems.

Article X.X.4.

Criteria or measurables for the welfare of broilers

Measurables can be based on the outcomes for the broiler (outcome based criteria) or the design of the system (resource or design based criteria). Outcome based measurables may give a better indication of welfare than

resource based measures because they reflect the complex interaction of several variables (e.g. experience and attitude of handlers and disease situation) that may be overlooked when relying on criteria that focus on the design of the system.

EU comment

At the end of the above paragraph of Art X.X.4, the following text should be added: "*However, resource-based measurable may be necessary to prevent poor animal welfare*".

Justification

EU supports the use of out-come based measures. However, resource based measures are a good tool to prevent poor welfare and should be used in combination.

It would be impractical at this time to assign numeric values to measurables (e.g. to specify a certain mortality rate as 'acceptable' or 'optimum', due to the large variations in the commercial production systems used by OIE Members. However, numeric values can be valuable in benchmarking performance. Benchmarking can be accomplished by evaluating the current incidence of outcome based measurables on commercial farms, and then determining the extent to which those problems can be reduced by management and genetic selection. Some measurables can be measured in the farm setting (e.g. gait, mortality and morbidity rates), while others are best measured at the slaughterhouse. For example, at slaughter *flocks* can be assessed for presence of bruising, broken limbs and injuries. The age of these lesions can help to determine the source (e.g. catching) (Nicol & Scott, 1990). Back scratching, hock and feet burns and breast blisters are also easily observed. Other conditions such as ascites, leg deformities, dehydration and disease conditions can be assessed. It is recommended that values for welfare measurables be determined with reference to appropriate national, sectoral or perhaps regional norms for commercial broiler production.

EU comment

In the above paragraph of Art X.X.4, the first three sentences should be deleted.

Justification

The current text is a mix of background and recommendations. Its objectives should be made clearer.

The following outcome based measurables are useful indicators of broiler welfare:

1. Mortality (dead, culled) and morbidity

   Daily, weekly and cumulative mortality (dead or culled) and morbidity rates should be within expected ranges. Any abrupt increase in the daily mortality or morbidity rate not connected to a specific *disease* could reflect an animal welfare problem.

EU comment

In Article X.X.4., paragraph 1, "*Mortality and morbidity*", the second sentence should be replaced by the following: *"Any ~~abrupt~~ unforeseen increase in the daily mortality or morbidity rate ~~not connected to a specific disease~~ could reflect an animal welfare problem*."

Justification

The changes may not have to be abrupt to reflect an animal welfare problem. Furthermore, even when such changes are caused by a specific disease it might reflect an animal welfare problem.

2. Gait

   Broilers are susceptible to developing a variety of infectious and non-infectious musculoskeletal disorders (see review in Mench, 2004). If severe these disorders may lead to overt lameness, and if less severe to gait abnormalities. Broilers that are lame or have more serious gait abnormalities may have difficulty reaching the food and water, may be trampled by other broilers, and may experience pain. Musculoskeletal problems

have many causes, including related to genetics, nutrition, sanitation, lighting, litter quality, and other environmental and management factors (see Mench, 2004; Dawkins et al., 2004). Broilers in commercial flocks should be assessed for gait abnormalities, and corrective actions identified to reduce the incidence of problems in subsequent flocks. There are several gait scoring systems available (Kestin et al., 1992; Garner et al., 2002; Webster et al., 2008; Weeks et al., 2002; Berg and Sanotra, 2003). Regardless of the scoring or assessment system used, broilers that are unable to access feed or water should be humanely euthanized as soon as possible after they have been observed.

3. Contact dermatitis

Contact dermatitis affects skin surfaces which have prolonged contact with litter or other flooring surfaces, the foot pad, rear surface of the hock and, when severe, the breast area. The conditions are manifested as blackened skin progressing to erosions and fibrosis on the lower surface of the foot pad, at the back of the hocks, and sometimes in the breast area. If severe the foot and hock lesions may contribute to lameness or serve as a portal of entry for secondary *infections*. Scoring systems for contact dermatitis have been developed (Welfare Quality®, 2009).

4. Feather condition

Evaluation of the feather condition of broilers provides useful information about aspects of welfare. Plumage dirtiness is correlated with both hock burns and lameness for individual birds (Arnould and Colin, 2009). Plumage dirtiness can be assessed when the broilers are caught for *transport* to the *slaughterhouse*. A scoring system has been developed for this purpose (RSPCA, 2008).

EU comment

In the second sentence of point 4, "*Feather condition*", in Article X.X.4, the words "*and naked area are*" should be included between "*plumage dirtiness* "and "*correlated*". The word "*is*" before correlated should be deleted.

Justification

Naked areas as result of feather peaking can also be used as welfare indicators.

5. Incidence of diseases, metabolic disorders and parasitic infestations

Ascites, sudden death syndrome and respiratory diseases (including infectious bronchitis, avian pneumovirus *infection* and mycoplasmosis) are of great economic and welfare significance in broilers (SCAHAW, 2000).

EU comment

In point 5 of Article X.X.4, the title could be limited to "*Incidence of diseases*".

Justification

Metabolic disorders and parasitic infestations are diseases.

6. Normal behaviour

Broiler behaviour can be a sensitive indicator of welfare problems.

6.1. Fear behaviour

Fearful broilers show avoidance of humans, and this behaviour is seen in *flocks* where *animal handlers* walk through the poultry house quickly when performing their tasks rather than moving more slowly while interacting with the broilers (Cransberg et al., 2000). Fearfulness (e.g. of sudden loud noises) can

also lead to the broilers piling on top of, and even suffocating, one another. Fearful broilers may be less productive (Hemsworth et al., 1994).

6.2. Spatial distribution

Changes in the spatial distribution of the birds may indicate thermal discomfort (e.g. broilers will huddle when they are cold) or the existence of areas of wet litter or uneven provision of light, food or water (if broilers are unevenly distributed).

6.3. Panting and wing spreading

Panting and wing spreading indicate heat stress.

6.4. Dust bathing

Dust bathing is an intricate body maintenance behaviour performed by many birds, including broilers (Olsson and Keeling, 2005). During a dust bathing bout, broilers work loose material (like litter in bedded systems) through their feathers. Dust bathing helps to keep the feathers in good condition, which in turns helps to maintain body temperature and protect against skin injury. Reduced dust bathing behaviour in the flock may indicate problems with litter or range quality, such as litter or ground that is wet or not friable.

6.5. Feeding, drinking and foraging

Reduced feeding or drinking behaviour can indicate management problems, including inadequate feeder or drinker space or placement, dietary imbalance, poor water quality, or feed contamination. Feeding and drinking behaviour are often depressed when broilers are ill, and feeding is also reduced during periods of heat stress and increased during cold stress. Foraging is the act of searching for food, typically by walking and pecking or scratching the litter substrate; reduced foraging activity could suggest problems with litter quality or presence of conditions that decrease bird movement (e.g. gait problems).

7. Abnormal behaviour - feather pecking and cannibalism

Feather pecking is the pecking or pulling of the feathers of other broilers, and can result in significant feather loss. Cannibalism is the tearing of the flesh of another bird, and can result in severe injury, and even the death of the pecked broiler. These are abnormal behaviours (Mench and Keeling, 2001; Rodenberg and Koene, 2004; Newberry, 2004) with multi-factorial causes that are not usually seen in commercial broiler stocks, although they can occur under some circumstances. Feather pecking may sometimes lead to cannibalism or may occur independently; once started, these problems can spread rapidly through the *flock*.

8. Water and feed consumption

Monitoring daily water consumption can be a useful tool to indicate disease and other welfare conditions, taking into consideration ambient temperature, relative humidity, feed consumption and other related factors. Problems with the water supply can result in wet litter, diarrhoea, or dehydration.

Changes in feed consumption can also indicate the presence of disease and other welfare conditions of the *flock* as well as suitability of the feed.

9. Performance

9.1. Growth rate - an index that indicates the average daily gain (gr) of weight per average broiler of a flock.

9.2. Feed conversion - an index that indicates the quantity of feed (kg) that is necessary for a gain of bodyweight of one kilogram of the average broiler of a *flock*.

9.3. Liveability - an index that indicates the percentage of broilers present at the end of the production period; more commonly this indicator is measured as its opposite: mortality (see point 1 of Article X.X.4.).

10. Injury rate

Broilers are susceptible to a number of injuries, and the rate of these injuries can indicate welfare problems in the flock. Injuries include those due to other broilers (scratches, feather loss or wounding due to feather pecking and cannibalism) and those due to environmental conditions (e.g. skin lesions) or humans. The most frequent injuries seen during catching are bruises, broken limbs and damaged wings. Fractures are located mainly on femur, radius, ulna, furcula and ischium. Dislocation of the femur at the hip joint is the most common traumatic injury.

11. Eye condition

Conjunctivitis can indicate the presence of irritants such as dust and ammonia. High ammonia levels will also cause corneal burns and eventual blindness (Morrow 2008:541).

EU comment

In the first sentence of point 11 in Article X.X.4, the words "*and eyes discharging and eyes swollen*" should be included after the words "*Conjunctivitis*".

Justification

Conjunctivitis is not the only eye pathology that could affect broilers.

~~The following outcome (animal) based measurables can be useful indicators of welfare The following outcome (animal) based measurables can be useful indicators of welfare and should be measured at appropriate times by the caretaker (in no particular order):~~

- ~~Mortality rate (dead, culled)~~
- ~~Gait~~
- ~~Contact dermatitis~~
- ~~Feather condition~~
- ~~Disease incidence / morbidity rates~~
- ~~Ascites / sudden death syndrome (SDS)~~
- ~~Respiratory disease~~
- ~~Parasitic diseases~~
- ~~Carcass and meat quality (condemnations)~~
- ~~Behaviour: fear, thermal distress, illness~~
  - ~~Human avoidance behaviour~~
  - ~~Spatial distribution:~~
  - ~~Panting and wing spreading.~~
  - ~~Dust bathing~~
  - ~~Feather pecking~~
  - ~~Cannibalism~~
  - ~~Feeding and drinking~~

- ~~Water consumption~~
- ~~Growth rate~~
- ~~Feed conversion~~
- ~~Injury rate~~
- ~~Eye condition.~~

Article X.X.5.

Recommendations

1. Biosecurity and animal health

1.1.~~a)~~ Biosecurity and disease prevention

Biosecurity means a set of measures designed to ~~protect a *flock* from the entry of infectious agents~~ maintain a *flock* at a particular health status and to prevent the entry (or exit) of specific infectious agents.

~~Biosecurity programmes should be implemented, commensurate with the risk of disease and in accordance with relevant recommendations found in Terrestrial Code chapters on OIE listed diseases.~~

Biosecurity programmes should be designed and implemented, commensurate with the desired flock health status and current disease risk (endemic and exotic or transboundary) that is specific to each epidemiological group of broilers and in accordance with relevant recommendations found in *Terrestrial Code* chapters on OIE listed diseases.

These programmes should address the control of the major routes for disease and pathogen transmission:

~~a) Poultry~~

~~b Other animals~~

~~c) People~~

~~d) Equipment~~

~~e) Vehicles.~~

a) direct transmission from other *poultry*, domesticated and wild animals and humans,

b) fomites, such as equipment, facilities and *vehicles*,

c) vectors (e.g., arthropods and rodents),

d) ~~vi~~ aerosols ~~Air,~~

e) ~~vii~~water supply,

f) ~~viii~~ feed.

Outcome based measurables: ~~disease~~ incidence of diseases, metabolic disorders and parasitic infestations, mortality ~~growth rate and feed conversion~~ and performance.

1.2.~~b)~~ Animal health management / preventive medicine / veterinary treatment

Animal health management means a system designed to ~~prevent diseases occurring in a *flock* and provide treatment if disease occurs in order to~~ optimise the health and welfare of the ~~*flock*~~ broilers. It includes prevention, treatment and control of *diseases* and adverse conditions.

Those responsible for the care of ~~birds~~ broilers should be aware of the signs of ill-health or distress, such as a change in ~~reduced food~~ feed and water intake, reduced growth, changes in behaviour,

abnormal ~~conditions~~ appearance of ~~their~~ feathers~~,~~ ~~or droppings~~ faeces, or other physical features.

If persons in charge are not able to identify the causes of ill-health or distress or to correct these or suspect the presence of a listed reportable disease, they should seek advice from those having training and experience, such as poultry *veterinarians* or other qualified advisers. Veterinary treatments should be prescribed by a qualified *veterinarian*.

There should be an effective programme for the prevention and treatment of *diseases* consistent with the programmes established by the *Veterinary Services* as appropriate.

Vaccinations and other administered treatments ~~to chickens~~ should be undertaken with consideration of the welfare of the ~~birds~~ broilers by people skilled in the procedures.

~~Culling of s~~ Sick or injured ~~birds~~ broilers should be ~~done in a humane manner~~ culled humanely as soon as possible. Similarly, killing broilers ~~birds as may be required~~ for diagnostic purposes should be done in a humane manner according to Chapter 7.6. of the *Terrestrial Code*.

Outcome based measurables: ~~disease~~ incidence of diseases, metabolic disorders and parasitic infestations, mortality and ~~poor~~ performance.

2. Environment and management

2.1. Thermal environment

~~In intensive and semi intensive production systems every attempt should be made to keep thermal conditions within the recommended range.~~

~~A table of recommended ranges will be included~~

Thermal conditions for broilers should be appropriate for their stage of development. For the growing stage the Thermal Heat Index (THI) can assist in identifying the comfort zones for the broilers at varying temperature and relative humidity levels.

When environmental conditions move outside these zones, various strategies can be used in different production systems to mitigate the adverse effects on the broilers: e.g. high air speeds and getting the birds to stand can alleviate the affects of high heat and humidity in intensive systems.

Ventilation should aim at controlling relative humidity to prevent the development of wet litter. Assessing litter condition on a regular basis is recommended.

Management of the thermal environment should be checked at least twice a day.

Outcome based measurables: normal and abnormal behaviour, mortality, contact dermatitis, water and feed consumption, performance, feather condition.

~~In extensive production systems appropriate management to mitigate the effects of extreme thermal conditions should be implemented.~~

~~Outcome based measurables: rates of mortality, rate of contact dermatitis, water consumption, feed consumption, growth rate, feed conversion and behaviour.~~

2.2. Lighting

There should be an adequate period of continuous darkness during each 24 hour period to allow the ~~birds~~ broilers to rest. There should also be an adequate period of continuous light. Reference should be made to relevant national, regional or international recommendations.

The light intensity during the light period should be sufficient and homogeneously distributed to allow the ~~chicks~~ broilers to find feed and water in the first few days after they are placed in the poultry

house, to stimulate ~~bird~~ activity, and ~~to~~ allow adequate inspection ~~of the birds~~.

EU comment

The EU would like to reiterate a comment previously submitted.

In the above point 2.b) of Art X.X.5, the first sentence above should be redrafted as follow:

"There should be adequate periods of darkness lasting at least 6 hours in total, with at least one uninterrupted period of darkness of at least 4 hours, excluding dimming periods, to allow the birds to rest".

Furthermore, in the second paragraph of the same point, the word "*sufficient*" should be replaced by "*of at least 20 lux during the lighting period, measured at bird eye level*".

Justification

Although it is very difficult to assign numeric values to measurable given the variations of production systems used by 177 OIE Members, nevertheless ranges should be indicated for parameters having relevant impact on the welfare of broilers.

There is a large body of science supporting the need for a prolonged dark period to allow birds to rest. Scientific studies concluded that except during the first days of life, welfare problems may arise if chickens receive less than 2 hours of darkness per day. Furthermore, various welfare problems are identified at light densities below 20 lux.

~~Birds~~ Broilers should be gradually adjusted to lighting changes.

Outcome based measurables: gait ~~lameness~~, metabolic disorders, performance ~~feed and water consumption~~, normal and abnormal behaviour and injur~~ies~~y rate.

2.3. Air quality

Adequate ventilation is required at all times to provide fresh air ~~and is one means of controlling temperature and humidity~~.

Ammonia concentration should not routinely exceed 25 ppm at ~~bird~~ broiler level (Kristenssen and Waathes, 2000; Jones et al., 2005).

Dust levels should be kept to a minimum. Methods for doing that can include maintaining appropriate ventilation and ~~optimal relative humidity~~ satisfactory litter moisture levels ~~(50% - 80%)~~. Where the health and welfare of broilers depends on an artificial ventilation system, provision should be made for an appropriate back-up power and alarm system.

Outcome based measurables: incidence of ~~respiratory~~ diseases, metabolic disorders and parasitic infestations (respiratory diseases), behaviour (panting, huddling), eye condition, ~~growth rate, feed conversion~~, performance, contact dermatitis and spatial distribution of the birds.

2.4. ~~Acoustic environment~~ Noise

Exposure of ~~birds~~ broilers to sudden or loud noises should be minimized where possible to prevent stress and fear reactions (e.g. piling).

~~Note: l~~ Location of farms should, where possible, take into account existing ~~environmental conditions~~ local sources of noise.

Outcome based measurables: daily mortality rate, morbidity, performance ~~growth rate, food conversion~~, injur~~ies~~y rate and ~~fearfulness and~~ fear behaviour.

2.5. Nutrition

Broilers ~~Birds~~ should always be fed a diet appropriate to their age and genetics, which contain~~ings~~ adequate nutrients to meet their requirements for good health.

Feed and water should be palatable and free from contaminants potentially hazardous to ~~bird~~ broiler health.

~~Cleaning~~ ~~t~~The water system should be cleaned ~~done~~ regularly to prevent growth of hazardous microorganisms.

Broilers ~~Birds~~ ~~must~~ should be provided with adequate access~~ibility~~ to feed on a daily basis. Water should be available continuously.

Special provisions should be made to enable young chicks ~~to~~ access to appropriate feed and water.

Outcome based measurables: feed and water consumption, performance ~~growth rate, food conversion~~, normal and abnormal behaviour, gait ~~lameness~~, ~~disease~~ incidence of diseases, metabolic disorders and parasitic infestations, mortality ~~morbidity~~ and ~~carcass and meat quality~~ injury rate.

2.6. Flooring, bedding, resting surfaces (litter quality)

The provision of loose material is desirable in order to encourage dust bathing and foraging.

EU comment

The EU appreciates that the comment on the need for litter has been taken in to account. However, the text could be further improved by adding the following text in the end of the above sentence in point 2.6) of Art X.X.5., "*This material should be dry and friable on the surface."*

Justification

In order to ensure a healthy environment for the broilers, it is important that the litter used is dry and friable.

Furthermore, the EU wishes to reiterate its previous comment.

The following sentence should be added at the end of the above paragraph:

"Fully slatted accommodation should preferably not be used as birds requires access to litter"

Justification

As a general principle, all broilers should be kept on litter. Although the EU recognises that farming systems without litter are still broadly used in other countries, the draft chapter should encourage its use in all systems.

Broilers need areas of litter to carry out their natural behaviours such as pecking and scratching. Therefore fully slatted housing systems should not be used.

The floor of a poultry house ~~building~~ should preferably be easy to clean and disinfect.

EU comment

In the above last sentence of point 2.6 of Art X.X.5, the word "*preferably"* should be deleted.

Justification

It is reasonable to ensure that the floor is easy to clean and disinfect for welfare reasons.

~~If l~~ Litter ~~is recycled it~~ should be managed to minimize any detrimental effects on welfare and health. Litter should be replaced or adequately treated when required to control a *disease outbreak* in the next *flock*.

Day-old birds chicks should be placed on a appropriate type of flooring housed on a floor suitable for their size to prevent injury. ~~Flooring conditions have an important impact on the welfare of chickens.~~

EU comment

In the above last paragraph of point 2.f) of Art X.X.5, the sentence "*Flooring conditions have an important impact on the welfare of chickens*" should be maintained.

The EU wishes to maintain the text "*housed on a floor suitable for their size*" and, reiterating its previous comment, the EU wishes "*floor suitable for their size*" to be better defined.

Justification

Flooring conditions have an important impact on the welfare of chickens.

If housed on litter based systems, before ~~the one~~ day-old birds ~~chicks~~ enter the ~~building~~ poultry house, the floor should have a bedding of uncontaminated ~~new~~ substrate (e.g. wood shavings, straw, shredded paper, treated used litter) of sufficient depth to elicit normal behaviour and to protect them from the floor.

Litter quality is partly related to the type of substrate used and partly to different management practices. The type of substrate should be chosen carefully. Litter should be maintained so that it is dry and friable and not dusty, caked or wet.

~~The floors of cages and slatted systems~~ Slatted floors should be designed, constructed and maintained to adequately support the ~~birds~~ broilers ~~and~~ prevent injuries and ~~to~~ ensure that manure can fall through or be adequately removed.

Outcome based measurables: contact dermatitis, ~~breast blisters~~ feather condition, metabolic disorders ~~ascites~~, gait ~~lameness~~, behaviour (dust bathing and foraging), eye condition, incidence of diseases, metabolic disorders and parasitic infestations (respiratory disease) and performance ~~growth rate~~.

2.7. Social environment

Management methods (e.g. reducing light intensity, providing foraging materials, nutritional modifications, reducing stocking density, selecting the appropriate genetic stock) should be implemented to reduce feather pecking and cannibalism in growing systems where these behaviours are a potential problem.

If these management strategies fail, therapeutic beak trimming should be considered as the last option and after a thorough investigation.

Outcome based measurables: injur~~ies~~y rate, normal and abnormal behaviour, feather condition and mortality~~, carcass and meat quality~~.

2.8. Stocking density

Broilers ~~chickens~~ should be housed ~~in~~ at an acceptable stocking density.

EU comment

The EU would like to reiterate its previous comment.

Although it is very difficult to assign numeric values to measurable given the variations of production systems used by 177 OIE Members, nevertheless the Community encourages OIE

to indicate ranges of acceptable stocking densities according to the different climatic and housing situations.

To determine the appropriate stocking density so that the floor space provided will ensure good welfare (comfort, ability to express normal postural adjustment and to access feed and water), the following factors should be taken into account: management capabilities, ambient conditions, housing system~~s~~, production~~s~~ system~~s~~, litter quality, ventilation, biosecurity strategy, ~~selection of~~ genetic stock~~s~~, and market age and weight of broilers ~~birds should be taken into account so that the floor space provided will ensure good welfare (comfort, ability to express normal postural adjustment and to access feed and water)~~.

Outcome based measurables: ~~rates of~~ injur~~ies~~y rate, ~~rates of~~ contact dermatitis, ~~rates of~~ mortality, normal and abnormal behaviour, performance and ~~growth rate, feed conversion~~, ~~plumage~~ feather condition ~~and carcass quality~~.

2.9. Outdoor areas

Broilers can be given access to outdoor areas as soon as they are old enough to range safely. There should be sufficient exit areas to allow birds to enter and leave the poultry house freely.

Management of outdoor areas is important in extensive and semi-intensive production systems. Land (pasture) management measures should be taken to reduce the risk of ~~birds~~ broilers being infected by parasites ~~transmitted~~. This might include limiting the stocking density and / or using several pieces of land consecutively (rotation).

Outdoor areas should be managed appropriately to minimize swampy conditions and mud. Outdoor areas should preferably be placed on well drained grounds.

Outdoor areas should be managed appropriately to ensure that they are free of poisonous plants and other contaminants.

Particularly in extensive systems where ~~birds~~ broilers do not have access to an indoor area, protection from adverse climatic conditions (e.g. heat, cold, rain) should be provided.

Outcome based measurables: normal and abnormal behaviour, incidence of parasitic infestations ~~diseases~~, performance ~~growth rate~~, contact dermatitis, feather condition ~~and~~ mortality ~~rate~~ and morbidity.

2.10. Protection from predators

Broilers should be protected from predators.

Outcome based measurables: fear behaviour, mortality and injur~~ies~~y rate.

~~3.~~ ~~Management~~

2.11. Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a strain for a particular location or production system.

Outcome based measurables: gait ~~lameness~~, metabolic disorders ~~ascites, sudden death syndrome (SDS),~~ mortality and performance ~~feed con version and growth rate~~.

2.12. Painful interventions

~~Commercial broilers chickens are not typically subjected to management practices that cause pain. However, prophylactic beak-trimming may be required in case of outbreaks of feather pecking and cannibalism, as described earlier. Guidelines for beak-trimming to minimize negative impacts on bird~~

~~health and performance are presented in Glatz and Miao (2005). Only the minimum amount of beak needed to prevent beak re-growth before market age (ideally, only the hook at the end of the upper beak) should be removed, and the trim should be performed so as to prevent subsequent distortion or deformation of the beak. The beak should be cauterized after cutting to minimise bleeding. Trimming at an early age (before 10 days of age; Hester and Shea-Moore, 2003) is preferred to prevent long-term pain, but since feather pecking and cannibalism develop when the birds are somewhat older prophylactic trimming will likely occur after this time.~~

~~There is a small specialty market for capons (castrated male broilers). Because the testes of male chickens are located inside the abdominal cavity, this procedure is a major surgery (Jacob and Mather, 2000) that should be performed only by skilled individuals and with measures to minimize pain, injury, and bleeding. The procedure is described in Jacob and Mather (2000).~~

Painful interventions (e.g. beak trimming, toe trimming, dubbing) should not be routinely practiced on broilers.

If therapeutic beak trimming is required, it should be carried out by trained and skilled personnel and care should be taken to remove the minimum amount of beak necessary using a method which minimizes pain and controls bleeding (Glatz and Miao, 2005; Hester and Shea-Moore, 2003).

Surgical caponisation should not be performed without adequate pain and *infection* control methods and should only be performed by *veterinarians* or trained and skilled personnel under veterinary supervision.

Outcome based measurables: use of any of the above procedures.

2.13. Handling and inspection

Broilers should be inspected at least twice ~~every~~ a day. ~~This~~ ~~i~~Inspection should have three main objectives: ~~to pick up dead birds;~~ 1) to identify sick or injured ~~birds~~ broilers to treat or cull them, ~~and~~ 2) to detect and correct any welfare or health problem in the *flock* (e.g. related to the supply of feed and water, thermal conditions, ventilation, litter quality), and 3) to pick up dead broilers.

Inspection should be done in such a way that ~~birds~~ broilers are not unnecessarily disturbed, for example ~~personnel *animal handlers*~~ should move quietly and slowly through the *flock*.

When ~~birds~~ broilers are handled they should not be injured or unnecessarily frightened or stressed.

~~Birds~~ Broilers which have an incurable sickness, significant deformity or injury should be removed from the *flock* and humanely killed as soon as possible.

Cervical dislocation is an acceptable method for killing small numbers of ~~birds~~ broilers if carried out competently (see Article 7.6.17. of the *Terrestrial Code*). For a complete description of killing methods see Article 7.6.~~17~~5. of the *Terrestrial Code*.

Outcome based measurables: normal and abnormal behaviour~~fear~~, performance, injur~~ies~~y rate, mortality and morbidity.

2.14. Personnel training

All people responsible for the broilers should receive appropriate training so that they are ~~be~~ competent ~~according to their~~ to carry out their responsibilities and should have sufficient knowledge of broiler behaviour, handling techniques, emergency euthanasia procedures, biosecurity, general signs of disease, and indicators of poor *animal welfare* such as stress and pain ~~and fatigue~~, and their alleviation.

Outcome based measurables: all measurables could apply.

2.15. Emergency Plans

~~Poultry~~ Broiler producers should have emergency plans to minimize and mitigate the consequences of:

natural disasters, *disease* outbreaks and the failure of mechanical equipment. Planning may include the provision of fail- safe alarm devices to detect malfunctions, back up generators, access to maintenance providers, alternative heating arrangements, ability to store water on farm, access to water cartage services, adequate on farm storage of feed and alternative feed supply and emergency ventilation.

An emergency plan for animal health should be developed consistent with national programs established or recommended by *Veterinary Services* as appropriate.

2.16. Location, construction and equipment of farms

The location of poultry farms should be chosen to be safe from the effects of fires and floods and other natural disasters to the extent practical. In addition farms should be sited to avoid or minimize biosecurity risks, exposure of birds to chemical and physical contaminants, noise and adverse climatic conditions.

~~Housing~~ Poultry houses, outdoor areas and equipment to which ~~poultry~~ broilers have access should be designed and maintained to avoid injury or pain to the birds.

~~Buildings~~ Poultry houses should be constructed and electrical and fuel installations should be fitted to minimise the risk of fire and other hazards.

~~Poultry~~ Broiler producers should have a maintenance programme in place for all equipment that, in case of failure, can jeopardize broiler welfare.

2.17. On farm harvesting

~~Feed~~ Broilers should not ~~be removed at a suitable~~ be subject to an excessive period of feed withdrawal ~~time~~ prior to ~~catching~~ the expected *slaughter* time.

Water should be available ~~for as long as possible~~ up to the time of catching.

~~Injured and sick birds~~ Broilers that are not fit for *transport* (severely injured or severely ill) should be culled ~~or separated~~ prior to harvesting the *flock*.

Catching should be carried out ~~done~~ by skilled ~~workers~~ *animal handlers* and every attempt should be made to minimize stress and fear reactions, and injury. If a broiler is injured during catching it should be culled.

~~The b~~ Broilers should not be picked up by their neck or wings.

~~The b~~ Broilers should be carefully p~~ut~~laced in the *transport container* ~~carefully~~.

Mechanical catchers, where used, should be designed, operated and maintained to minimize injury, stress and fear to the ~~birds~~ broilers. A c~~C~~ontingency plan is advisable in case of mechanical failure.

Catching should preferably be carried out under dim or blue light to calm the broilers ~~birds~~.

Catching should be scheduled to minimize the time to *slaughter* as well as climatic stress during catching, *transport* and holding.

Stocking density in *transport containers* should suit climatic conditions and maintain comfort.

Containers should be clean and disinfected and designed and maintained to avoid injury to the broilers ~~birds~~.

Outcome based measurables: ~~incidence of~~ injur~~ies~~y rate and mortality rate (dead on arrival) ~~and carcass quality~~.

EU comment

In the above last sentence of point 2.17 of Art X.X.5, the EU wishes the OIE to clarify if death during catching should be included in the morality rate.

2.18. Humane killing

Injured and sick birds should be killed humanely.

Cervical dislocation is considered a humane method for killing small numbers of broilers ~~birds~~ (see Article 7.6.17. of the *Terrestrial Code*).

For a description of other methods for the humane killing of broilers see Article 7.6.5. of the *Terrestrial Code*.

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